Clinical trial results:
A Phase III, randomized, multicenter, parallel-group, non-inferiority, open-label study evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long acting rilpivirine from current INI- NNRTI-, or PI-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed

Summary

EudraCT number	2016-001647-39
Trial protocol	ES DE SE IT
Global end of trial date	

Results information

Result version number	v1
This version publication date	09 June 2019
First version publication date	09 June 2019

Trial information

Trial identification

Sponsor protocol code	201585

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ViiV Healthcare
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Reponse Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Reponse Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	14 September 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 May 2018
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferior antiviral activity of switching to intramuscular CAB LA + RPV LA every 4 weeks (monthly) compared to continuation of current first line antiretroviral regimen over 48 weeks in HIV-1 infected antiretroviral therapy (ART)- experienced participants

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 October 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 16
Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	Canada: 34
Country: Number of subjects enrolled	France: 32
Country: Number of subjects enrolled	Germany: 48
Country: Number of subjects enrolled	Italy: 28
Country: Number of subjects enrolled	Mexico: 10
Country: Number of subjects enrolled	Korea, Republic of: 19
Country: Number of subjects enrolled	Russian Federation: 106
Country: Number of subjects enrolled	South Africa: 71
Country: Number of subjects enrolled	Spain: 62
Country: Number of subjects enrolled	Sweden: 15
Country: Number of subjects enrolled	United States: 156
Worldwide total number of subjects	616
EEA total number of subjects	185

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	601
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a phase III, randomized, open-label, active-controlled, multi-center, parallel-group, non-inferiority study to evaluate the antiviral activity and safety of two long-acting (LA) injectable drugs, cabotegravir (CAB) plus rilpivirine (RPV) when compared to current standard of care conducted in virologically suppressed human immunodeficiency.

Pre-assignment

Screening details:

A total of 618 participants were enrolled in the study. Two randomized participants did not receive study treatment. A total of 616 participants contributed to the Intent-to-treat exposed Population and Safety Population. The results presented are based on Week 48 primary analysis.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	CAB LA+RPV LA (Q4W)

Arm description:

During Maintenance phase (Day 1-Week 52), participants received oral CAB 30 milligram (mg)+RPV 25 mg once daily from Day 1 for 4 weeks. At Week 4B, the participants were given the last dose of oral CAB+RPV and the first dose of CAB LA 600 mg+RPV LA 900 mg injections within 2 hours of the final oral dose. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg every four weeks (Q4W) through Week 52. After completion of Maintenance phase, participants who chose to enter Extension phase continued to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period

Arm type	Experimental
Investigational medicinal product name	Carbotegravir oral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received both CAB 30 mg tablets once daily from Day 1 to Week 4b approximately the same time each day with a meal

Investigational medicinal product name	Rilpivirine oral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Buccal tablet, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received both RPV 25 mg tablets once daily from Day 1 to Week 4b approximately the same time each day with a meal

Investigational medicinal product name	Carbotegravir Injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received CAB 3 mL IM injection at Week 4b after the last dose of CAB oral regimen. Participants then received CAB 2 milliliter(mL) injections every 4 weeks from Week 8 to Week 52

Investigational medicinal product name	Rilpivirine Injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received RPV 3 mL IM injection at Week 4b after the last dose of RPV oral regimen. Participants then received RPV 2 mL injections every 4 weeks from Week 8 to Week 52

Arm title	Current ART

Arm description:

During Maintenance phase (Day 1 - Week 52), participants continued to receive current antiretroviral therapy (ART) (protease inhibitor [PI] or integrase inhibitor [INI] or non-nucleoside reverse transcriptase inhibitor [NNRTI]) plus 2 NRTIs for 52 weeks. After completion of the Maintenance phase, participants who chose to enter the Extension phase switched to CAB LA+RPV LA

Arm type	Active comparator
Investigational medicinal product name	Current anti-retroviral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 2 NRTIs + INI or 2 NRTIs + NNRTI or 2 NRTIs + PI once daily from Day 1 to Week 52.

Number of subjects in period 1	CAB LA+RPV LA (Q4W)	Current ART
Started	308	308
Completed	281	290
Not completed	27	18
Adverse event, serious fatal	-	1
Consent withdrawn by subject	1	5
Physician decision	2	-
Adverse event, non-fatal	13	4
Ongoing	1	-
Protocol-specified withdrawal criterion	1	-
Lost to follow-up	1	1
Protocol deviation	5	3
Lack of efficacy	3	4

Baseline characteristics

Reporting groups

Reporting group title	CAB LA+RPV LA (Q4W)

Reporting group description:

During Maintenance phase (Day 1-Week 52), participants received oral CAB 30 milligram (mg)+RPV 25 mg once daily from Day 1 for 4 weeks. At Week 4B, the participants were given the last dose of oral CAB+RPV and the first dose of CAB LA 600 mg+RPV LA 900 mg injections within 2 hours of the final oral dose. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg every four weeks (Q4W) through Week 52. After completion of Maintenance phase, participants who chose to enter Extension phase continued to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period

Reporting group title	Current ART

Reporting group description:

During Maintenance phase (Day 1 - Week 52), participants continued to receive current antiretroviral therapy (ART) (protease inhibitor [PI] or integrase inhibitor [INI] or non-nucleoside reverse transcriptase inhibitor [NNRTI]) plus 2 NRTIs for 52 weeks. After completion of the Maintenance phase, participants who chose to enter the Extension phase switched to CAB LA+RPV LA

Reporting group values	CAB LA+RPV LA (Q4W)	Current ART	Total
Number of subjects	308	308	616
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	303	298	601
From 65-84 years	5	10	15
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	41.6	43.2	
standard deviation	± 9.99	± 11.43	-
Sex: Female, Male Units: Subjects			
Female	99	104	203
Male	209	204	413
Race/Ethnicity, Customized Units: Subjects			
American Indian (AI) or Alaska Native (AN)	8	8	16
Asian-Central South Asian Heritage	1	0	1
Asian-Japanese/East/South-East Asian Heritage	21	13	34
Black or African American	62	77	139
Native Hawaiian or other Pacific Islander	0	1	1

White	214	207	421
AI or AN & Black/African American	0	1	1
AI or AN & Black/African American & White	1	1	2
Black/African American or White	1	0	1

End points reporting groups

Reporting group title	CAB LA+RPV LA (Q4W)

Reporting group description:

During Maintenance phase (Day 1-Week 52), participants received oral CAB 30 milligram (mg)+RPV 25 mg once daily from Day 1 for 4 weeks. At Week 4B, the participants were given the last dose of oral CAB+RPV and the first dose of CAB LA 600 mg+RPV LA 900 mg injections within 2 hours of the final oral dose. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg every four weeks (Q4W) through Week 52. After completion of Maintenance phase, participants who chose to enter Extension phase continued to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period

Reporting group title	Current ART

Reporting group description:

During Maintenance phase (Day 1 - Week 52), participants continued to receive current antiretroviral therapy (ART) (protease inhibitor [PI] or integrase inhibitor [INI] or non-nucleoside reverse transcriptase inhibitor [NNRTI]) plus 2 NRTIs for 52 weeks. After completion of the Maintenance phase, participants who chose to enter the Extension phase switched to CAB LA+RPV LA

Subject analysis set title	CAB LA
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received IM injections of CAB LA 400 mg every four weeks through Week 52.

Subject analysis set title	RPV LA
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received IM injections of RPV LA 900 mg every four weeks through Week 52.

Primary: Number of participants with virologic failure (HIV-1 ribonucleic acid [RNA] >=50 copies per milliliter [c/mL]) using snapshot algorithm at Week 48

End point title	Number of participants with virologic failure (HIV-1 ribonucleic acid [RNA] >=50 copies per milliliter [c/mL]) using snapshot algorithm at Week 48

End point description:

Number of participants with virologic failure endpoint (HIV-1 RNA>=50 c/mL) as per Food and Drug Administration (FDA) snapshot algorithm at Week 48 was assessed to demonstrate the non-inferior antiviral activity of switching to intramuscular (IM) CAB LA+RPV LA every 4 weeks compared to continuation of current ART regimen over 48 weeks in HIV-1 infected ART-experienced participants. The HIV-1 RNA >=50 copies/mL per snapshot algorithm was determined by the last available on-treatment HIV-1 RNA measurement within the analysis visit window of interest. Intent-to treat exposed (ITT-E) participants included all randomized participants who received at least one dose of Investigational Product (IP) during the maintenance phase. Participants were analyzed according to the randomized treatment regardless of what treatment actually received

End point type	Primary

End point timeframe:

Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[1]	308[2]		
Units: Participants	5	3		

Notes:

[1] - ITT-E Population.

[2] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Non-inferiority in the proportion of participants with virologic failure at Week 48 (per FDA's snapshot algorithm for assessing HIV-1 RNA >=50 copies/mL) can be concluded if the upper bound of a two-sided 95% confidence interval for the difference in failure rates between the two treatment arms (CAB – current ART) is not more than 6%.

Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Adjusted difference in proportion
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	2.5

Notes:

[3] - Adjusted difference in proportion was based on Cochran-Mantel Haenszel stratified analysis adjusting for the following Baseline stratification factors: sex at birth (Male, Female) and Baseline third agent (PI, NNRTI, INI).

Secondary: Number of participants with HIV-1 RNA <50 copies/mL using snapshot algorithm at Week 48

End point title	Number of participants with HIV-1 RNA <50 copies/mL using snapshot algorithm at Week 48

End point description:

Plasma samples were collected for quantitative analysis of HIV-1 RNA. Number of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 using FDA snapshot algorithm was assessed to demonstrate antiviral and immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to continuation of current ART. The HIV-1 RNA <50 copies/mL per snapshot algorithm was determined by the last available on-treatment HIV-1 RNA measurement within the analysis visit window of interest.

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[4]	308[5]		
Units: Participants	285	294		

Notes:

[4] - ITT-E Population

[5] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Non-inferiority in the proportion of participants with HIV-1 RNA<50 c/mL at Week 48 (per FDA's snapshot algorithm) can be concluded if the lower bound of a two-sided 95% confidence interval for the difference in success rates between the two treatment arms (CAB – current ART) is more than -10%.

Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Adjusted difference in proportion
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	0.7

Notes:

[6] - Adjusted difference in proportion was based on Cochran-Mantel Haenszel stratified analysis adjusting for the following Baseline stratification factors: sex at birth (Male, Female) and Baseline third agent (PI, NNRTI, INI).

Secondary: Number of participants with HIV-1 RNA <200 copies/mL using snapshot algorithm at Week 48

End point title	Number of participants with HIV-1 RNA <200 copies/mL using snapshot algorithm at Week 48

End point description:

Number of participants with plasma HIV-1 RNA <200 copies/mL at Week 48 using the snapshot algorithm was assessed based on the antiviral and immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to continuation of current ART.

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[7]	308[8]		
Units: Participants	286	295		

Notes:

[7] - ITT-E Population

[8] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with confirmed virologic failure (CVF)

End point title	Number of participants with confirmed virologic failure (CVF)

End point description:

The CVF is defined as rebound as indicated by two consecutive plasma HIV-1-RNA levels >=200 copies/mL after prior suppression to <200 copies/mL. The outcome displays only visits during which at least one new CVF occurs. Plasma samples were collected for quantitative analysis of HIV-1 RNA.

End point type	Secondary

End point timeframe:

Weeks 8, 12, 20, 24, 32 and 40

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[9]	308[10]		
Units: Participants				
Week 8	1	0		
Week 12	2	0		
Week 20	2	2		
Week 24	3	2		
Week 32	3	3		
Week 40	3	4		

Notes:

[9] - ITT-E Population

[10] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for plasma HIV-1 RNA at Week 48

End point title	Absolute values for plasma HIV-1 RNA at Week 48

End point description:

Logarithm to base 10 (log10) values for plasma HIV-1 RNA has been presented. Only those participants with data available at the specified data points were analyzed

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	265[11]	292[12]		
Units: log10 copies/mL				
arithmetic mean (standard deviation)	1.505 (± 0.0470)	1.518 (± 0.1123)		

Notes:

[11] - ITT-E Population

[12] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for plasma HIV-1 RNA

End point title	Change from Baseline values for plasma HIV-1 RNA

End point description:

Plasma for quantitative HIV-1 RNA were collected at indicated time points. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as: HIV-1 RNA(log 10) at Week 48 - HIV-1 RNA(log 10) at Baseline.

End point type	Secondary

End point timeframe:

Baseline and Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	265[13]	292[14]		
Units: log10 copies/mL				
arithmetic mean (standard deviation)	-0.013 (± 0.1940)	0.012 (± 0.1201)		

Notes:

[13] - ITT-E Population

[14] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for CD4+ lymphocyte count at Week 48

End point title	Absolute values for CD4+ lymphocyte count at Week 48

End point description:

Blood samples were collected and CD4+ cell count assessment by flow cyclometry was carried out to evaluate the immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to current ART. Only those participants with data available at the specified data points were analyzed

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	263[15]	290[16]		
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)	685.3 (± 262.97)	716.7 (± 292.85)		

Notes:

[15] - ITT-E Population

[16] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for CD4+ lymphocyte count at Week 48

End point title	Change from Baseline values for CD4+ lymphocyte count at Week 48

End point description:

Blood samples were collected and CD4+ cell count assessment by flow cyclometry was carried out to evaluate the immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to current ART.Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value at Week 48 minus Baseline value. Only those participants with data available at the specified data points were analyzed

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	263[17]	290[18]		
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)	9.9 (± 187.24)	19.4 (± 168.80)		

Notes:

[17] - ITT-E Population

[18] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with disease progression

End point title	Number of participants with disease progression

End point description:

Disease progression was defined as HIV-associated conditions, acquired immunodeficiency syndrome (AIDS), and death through 48 Weeks. Data of participants who experienced disease progression to Centers for Disease Control and Prevention (CDC) Stage III or death has been presented.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[19]	308[20]		
Units: Participants	8	8		

Notes:

[19] - ITT-E Population

[20] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with non-serious adverse events (non-SAEs) and serious adverse events (SAEs)

End point title	Number of participants with non-serious adverse events (non-SAEs) and serious adverse events (SAEs)

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. A SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity, is a congenital anomaly/birth defect, associated with liver injury and impaired liver function or any other situations as per medical or scientific judgement. Safety Population comprised of all randomized participants who received at least one dose of IP during the maintenance phase of the study (on or after Day 1 visit). Participants will be assessed according to actual treatment received.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[21]	308[22]		
Units: Participants				
Any non-SAE	263	117		
Any SAE	13	14		

Notes:

[21] - Safety Population

[22] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with severity of adverse events

End point title	Number of participants with severity of adverse events

End point description:

Severity of AEs were defined as per The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table) Version 2.0, November 2014. Severity grades for AEs were as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (Potentially life-threatening) and Grade 5 were all deaths related to an AE.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[23]	308[24]		
Units: Participants				
Grade 1	101	115		
Grade 2	158	81		
Grade 3	27	19		
Grade 4	8	4		
Grade 5	0	1		

Notes:

[23] - Safety Population

[24] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters over time including Week 48: basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets

End point title	Absolute values for hematology parameters over time including Week 48: basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets

End point description:

Blood samples were collected for the analysis of hematology parameters including basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[25]	308[26]		
Units: 10^9 cells per liter				
arithmetic mean (standard deviation)				
Basophils, Baseline, n=308, 307	0.021 (± 0.0147)	0.021 (± 0.0148)		
Basophils, Week 4, n=299, 291	0.024 (± 0.0153)	0.023 (± 0.0161)		
Basophils, Week 8, n=216, 294	0.023 (± 0.0188)	0.022 (± 0.0155)		
Basophils, Week 12, n=293, 290	0.022 (± 0.0154)	0.022 (± 0.0157)		
Basophils, Week 16, n=274, 292	0.022 (± 0.0147)	0.022 (± 0.0140)		
Basophils, Week 20, n=273, 292	0.023 (± 0.0182)	0.024 (± 0.0195)		
Basophils, Week 24, n=277, 292	0.023 (± 0.0139)	0.024 (± 0.0133)		
Basophils, Week 28, n=266, 295	0.024 (± 0.0150)	0.023 (± 0.0138)		
Basophils, Week 32, n=262, 283	0.025 (± 0.0171)	0.024 (± 0.0159)		
Basophils, Week 36, n=260, 282	0.029 (± 0.0211)	0.028 (± 0.0190)		
Basophils, Week 40, n=258, 280	0.035 (± 0.0266)	0.031 (± 0.0206)		
Basophils, Week 44, n=258, 268	0.037 (± 0.0275)	0.033 (± 0.0222)		
Basophils, Week 48, n=246, 274	0.040 (± 0.0253)	0.039 (± 0.0249)		
Eosinophils, Baseline, n=308, 307	0.142 (± 0.1409)	0.140 (± 0.1538)		
Eosinophils, Week 4, n=299, 291	0.168 (± 0.1587)	0.145 (± 0.1422)		
Eosinophils, Week 8, n=216, 294	0.154 (± 0.1379)	0.131 (± 0.1333)		
Eosinophils, Week 12, n=293, 290	0.142 (± 0.1172)	0.132 (± 0.1471)		
Eosinophils, Week 16, n=274, 292	0.153 (± 0.1395)	0.131 (± 0.1584)		
Eosinophils, Week 20, n=273, 292	0.152 (± 0.1480)	0.116 (± 0.1094)		
Eosinophils, Week 24, n=277, 292	0.143 (± 0.1323)	0.121 (± 0.1337)		
Eosinophils, Week 28, n=266, 295	0.144 (± 0.1266)	0.129 (± 0.1320)		
Eosinophils, Week 32, n=262, 283	0.170 (± 0.1643)	0.131 (± 0.1319)		
Eosinophils, Week 36, n=260, 282	0.150 (± 0.1403)	0.132 (± 0.1162)		
Eosinophils, Week 40, n=258, 280	0.161 (± 0.1206)	0.132 (± 0.1124)		
Eosinophils, Week 44, n=258, 268	0.175 (± 0.1471)	0.136 (± 0.1126)		
Eosinophils, Week 48, n=246, 274	0.174 (± 0.1412)	0.140 (± 0.1265)		
Leukocytes, Baseline, n=308, 307	5.87 (± 1.928)	5.65 (± 1.897)		
Leukocytes, Week 4, n=300, 298	6.43 (± 2.154)	5.81 (± 1.733)		
Leukocytes, Week 8, n=217, 301	6.14 (± 1.875)	5.64 (± 1.663)		

Leukocytes, Week 12, n=294, 293	6.24 (± 1.876)	5.77 (± 1.751)		
Leukocytes, Week 16, n=279, 295	6.27 (± 1.920)	5.82 (± 1.756)		
Leukocytes, Week 20, n=276, 298	6.27 (± 1.947)	5.70 (± 1.721)		
Leukocytes, Week 24, n=279, 294	6.18 (± 1.931)	5.78 (± 1.756)		
Leukocytes, Week 28, n=268, 297	6.08 (± 1.949)	5.73 (± 1.637)		
Leukocytes, Week 32, n=267, 288	6.30 (± 1.914)	5.73 (± 1.666)		
Leukocytes, Week 36, n=264, 285	6.14 (± 1.831)	5.80 (± 1.968)		
Leukocytes, Week 40, n=264, 286	6.24 (± 2.046)	5.74 (± 1.713)		
Leukocytes, Week 44, n=269, 279	6.15 (± 1.884)	5.66 (± 1.745)		
Leukocytes, Week 48, n=252, 282	6.01 (± 1.943)	5.62 (± 1.679)		
Lymphocytes, Baseline, n=308, 307	1.943 (± 0.6073)	1.940 (± 0.6880)		
Lymphocytes, Week 4, n=299, 291	2.127 (± 0.6942)	2.059 (± 0.6929)		
Lymphocytes, Week 8, n=216, 294	1.995 (± 0.6347)	1.975 (± 0.6549)		
Lymphocytes, Week 12, n=293, 290	1.984 (± 0.6428)	2.026 (± 0.6996)		
Lymphocytes, Week 16, n=274, 292	2.057 (± 0.6840)	2.029 (± 0.6584)		
Lymphocytes, Week 20, n=273, 292	2.035 (± 0.6140)	2.030 (± 0.6906)		
Lymphocytes, Week 24, n=277, 292	2.016 (± 0.6523)	1.980 (± 0.6047)		
Lymphocytes, Week 28, n=266, 295	2.049 (± 0.6960)	2.016 (± 0.6476)		
Lymphocytes, Week 32, n=262, 283	2.020 (± 0.6157)	2.007 (± 0.6511)		
Lymphocytes, Week 36, n=260, 282	1.960 (± 0.6009)	1.984 (± 0.6444)		
Lymphocytes, Week 40, n=258, 280	1.994 (± 0.6149)	1.957 (± 0.6305)		
Lymphocytes, Week 44, n=258, 268	2.016 (± 0.6457)	1.970 (± 0.6219)		
Lymphocytes, Week 48, n=246, 274	1.900 (± 0.5725)	1.915 (± 0.6204)		
Neutrophils, Baseline, n=308, 307	3.437 (± 1.6106)	3.209 (± 1.5748)		
Neutrophils, Week 4, n=299, 291	3.708 (± 1.8763)	3.244 (± 1.3931)		
Neutrophils, Week 8, n=216, 294	3.597 (± 1.6128)	3.190 (± 1.3370)		
Neutrophils, Week 12, n=293, 290	3.724 (± 1.5751)	3.268 (± 1.4153)		
Neutrophils, Week 16, n=274, 292	3.670 (± 1.6777)	3.308 (± 1.3870)		
Neutrophils, Week 20, n=273, 292	3.707 (± 1.6532)	3.188 (± 1.3345)		
Neutrophils, Week 24, n=277, 292	3.613 (± 1.5978)	3.289 (± 1.4381)		
Neutrophils, Week 28, n=266, 295	3.528 (± 1.5464)	3.221 (± 1.2962)		
Neutrophils, Week 32, n=262, 283	3.704 (± 1.6196)	3.228 (± 1.2909)		
Neutrophils, Week 36, n=260, 282	3.629 (± 1.5688)	3.314 (± 1.6341)		
Neutrophils, Week 40, n=258, 280	3.688 (± 1.7685)	3.280 (± 1.4190)		
Neutrophils, Week 44, n=258, 268	3.571 (± 1.5425)	3.169 (± 1.4140)		

Neutrophils, Week 48, n=246, 274	3.450 (± 1.5649)	3.172 (± 1.3627)		
Monocytes, Baseline, n=308, 307	0.353 (± 0.1745)	0.339 (± 0.1596)		
Monocytes, Week 4, n=299, 291	0.404 (± 0.1951)	0.367 (± 0.1694)		
Monocytes, Week 8, n=216, 294	0.369 (± 0.1628)	0.358 (± 0.1875)		
Monocytes, Week 12, n=293, 290	0.375 (± 0.1563)	0.342 (± 0.1693)		
Monocytes, Week 16, n=274, 292	0.364 (± 0.1537)	0.345 (± 0.1645)		
Monocytes, Week 20, n=273, 292	0.356 (± 0.1526)	0.342 (± 0.1632)		
Monocytes, Week 24, n=277, 292	0.370 (± 0.1632)	0.341 (± 0.1632)		
Monocytes, Week 28, n=266, 295	0.354 (± 0.1631)	0.333 (± 0.1592)		
Monocytes, Week 32, n=262, 283	0.378 (± 0.1629)	0.351 (± 0.1801)		
Monocytes, Week 36, n=260, 282	0.376 (± 0.1593)	0.366 (± 0.1824)		
Monocytes, Week 40, n=258, 280	0.402 (± 0.1612)	0.359 (± 0.1823)		
Monocytes, Week 44, n=258, 268	0.409 (± 0.1643)	0.388 (± 0.1795)		
Monocytes, Week 48, n=246, 274	0.407 (± 0.1600)	0.384 (± 0.1742)		
Platelets, Baseline, n=308, 308	231.1 (± 56.75)	232.9 (± 59.28)		
Platelets, Week 4, n=300, 298	233.5 (± 55.09)	238.1 (± 61.98)		
Platelets, Week 8, n=216, 298	227.4 (± 47.04)	234.0 (± 61.84)		
Platelets, Week 12, n=294, 290	230.2 (± 57.32)	237.8 (± 64.42)		
Platelets, Week 16, n=279, 294	226.1 (± 56.82)	236.4 (± 61.63)		
Platelets, Week 20, n=274, 297	226.5 (± 58.11)	237.7 (± 61.51)		
Platelets, Week 24, n=279, 292	224.9 (± 53.19)	239.8 (± 64.11)		
Platelets, Week 28, n=268, 295	224.7 (± 54.15)	239.0 (± 62.32)		
Platelets, Week 32, n=267, 289	226.5 (± 50.84)	239.3 (± 59.53)		
Platelets, Week 36, n=267, 284	229.0 (± 53.90)	242.9 (± 66.12)		
Platelets, Week 40, n=263, 288	230.1 (± 53.48)	240.8 (± 61.92)		
Platelets, Week 44, n=270, 286	235.5 (± 55.80)	241.4 (± 61.73)		
Platelets, Week 48, n=253, 281	230.5 (± 54.33)	240.2 (± 62.95)		

Notes:

[25] - Safety Population

[26] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters: erythrocyte mean corpuscular volume

End point title	Absolute values for hematology parameters: erythrocyte mean corpuscular volume

End point description:

Blood samples were collected for the analysis of hematology parameter including erythrocyte mean corpuscular volume at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[27]	308[28]		
Units: Femtoliters				
arithmetic mean (standard deviation)				
Baseline, n=308, 308	95.7 (± 7.97)	96.6 (± 9.35)		
Week 4, n=300, 300	94.6 (± 6.88)	96.9 (± 9.31)		
Week 8, n=218, 301	92.7 (± 5.76)	96.8 (± 9.25)		
Week 12, n=294, 293	91.7 (± 5.69)	96.9 (± 9.34)		
Week 16, n=280, 296	90.6 (± 5.48)	96.8 (± 9.64)		
Week 20, n=276, 298	90.3 (± 5.37)	97.0 (± 9.63)		
Week 24, n=279, 294	90.2 (± 5.44)	96.9 (± 9.75)		
Week 28, n=268, 297	90.2 (± 5.68)	97.2 (± 9.77)		
Week 32, n=268, 291	90.1 (± 5.55)	96.7 (± 9.36)		
Week 36, n=267, 288	89.8 (± 5.64)	96.5 (± 9.08)		
Week 40, n=264, 289	89.9 (± 5.57)	96.5 (± 9.05)		
Week 44, n=273, 286	89.9 (± 5.52)	96.2 (± 9.08)		
Week 48, n=255, 284	89.9 (± 5.58)	96.2 (± 9.38)		

Notes:

[27] - Safety Population

[28] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters: erythrocytes

End point title	Absolute values for hematology parameters: erythrocytes

End point description:

Blood samples were collected for the analysis of hematology parameters including erythrocytes at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[29]	308[30]		
Units: 10^12 cells per liter				
arithmetic mean (standard deviation)				
Baseline, n=308, 308	4.55 (± 0.563)	4.49 (± 0.570)		
Week 4, n=300, 300	4.59 (± 0.503)	4.45 (± 0.567)		
Week 8, n=218, 301	4.68 (± 0.479)	4.49 (± 0.566)		
Week 12, n=294, 293	4.79 (± 0.464)	4.51 (± 0.580)		
Week 16, n=280, 296	4.84 (± 0.475)	4.48 (± 0.549)		
Week 20, n=276, 298	4.86 (± 0.459)	4.48 (± 0.586)		
Week 24, n=279, 294	4.86 (± 0.471)	4.48 (± 0.572)		
Week 28, n=268, 297	4.85 (± 0.456)	4.47 (± 0.565)		
Week 32, n=268, 291	4.84 (± 0.452)	4.48 (± 0.550)		
Week 36, n=267, 288	4.81 (± 0.462)	4.49 (± 0.561)		
Week 40, n=264, 289	4.84 (± 0.456)	4.49 (± 0.572)		
Week 44, n=273, 286	4.86 (± 0.448)	4.49 (± 0.572)		
Week 48, n=255, 284	4.81 (± 0.448)	4.50 (± 0.600)		

Notes:

[29] - Safety Population

[30] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters: hemoglobin

End point title	Absolute values for hematology parameters: hemoglobin

End point description:

Blood samples were collected for the analysis of hematology parameter including hemoglobin at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[31]	308[32]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Baseline, n=308, 308	142.2 (± 17.24)	141.4 (± 16.29)		
Week 4, n=300, 300	141.7 (± 16.30)	140.5 (± 16.44)		

Week 8, n=218, 301	141.5 (± 16.08)	141.2 (± 16.51)		
Week 12, n=294, 293	142.4 (± 15.90)	141.6 (± 16.62)		
Week 16, n=280, 296	142.5 (± 16.19)	140.5 (± 15.81)		
Week 20, n=276, 298	142.6 (± 15.52)	141.2 (± 16.62)		
Week 24, n=279, 294	143.3 (± 15.66)	141.6 (± 16.18)		
Week 28, n=268, 297	142.8 (± 16.05)	140.9 (± 15.89)		
Week 32, n=268, 291	143.0 (± 15.42)	141.8 (± 15.81)		
Week 36, n=267, 288	142.7 (± 16.31)	142.3 (± 15.72)		
Week 40, n=264, 289	143.5 (± 15.80)	142.4 (± 15.90)		
Week 44, n=273, 286	143.6 (± 15.66)	142.1 (± 16.38)		
Week 48, n=255, 284	142.7 (± 15.93)	142.8 (± 16.34)		

Notes:

[31] - Safety Population

[32] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters: hematocrit

End point title	Absolute values for hematology parameters: hematocrit

End point description:

Blood samples were collected for the analysis of hematology parameters including hematocrit at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[33]	308[34]		
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Baseline, n=308, 308	0.4333 (± 0.04804)	0.4305 (± 0.04454)		
Week 4, n=300, 300	0.4325 (± 0.04570)	0.4283 (± 0.04548)		
Week 8, n=218, 301	0.4327 (± 0.04570)	0.4310 (± 0.04580)		
Week 12, n=294, 293	0.4379 (± 0.04483)	0.4338 (± 0.04640)		

Week 16, n=280, 296	0.4369 (± 0.04626)	0.4304 (± 0.04418)		
Week 20, n=276, 298	0.4378 (± 0.04476)	0.4312 (± 0.04755)		
Week 24, n=279, 294	0.4376 (± 0.04589)	0.4312 (± 0.04595)		
Week 28, n=268, 297	0.4364 (± 0.04607)	0.4308 (± 0.04555)		
Week 32, n=268, 291	0.4350 (± 0.04311)	0.4299 (± 0.04431)		
Week 36, n=267, 288	0.4311 (± 0.04462)	0.4295 (± 0.04348)		
Week 40, n=264, 289	0.4342 (± 0.04381)	0.4300 (± 0.04449)		
Week 44, n=273, 286	0.4357 (± 0.04288)	0.4282 (± 0.04472)		
Week 48, n=255, 284	0.4318 (± 0.04438)	0.4286 (± 0.04465)		

Notes:

[33] - Safety Population

[34] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets

End point title	Change from Baseline for hematology parameters: basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets

End point description:

Blood samples were collected for the analysis of hematology parameters including basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[35]	308[36]		
Units: 10^9 cells per liters				
arithmetic mean (standard deviation)				
Basophils, Week 4, n=299, 290	0.003 (± 0.0202)	0.003 (± 0.0185)		
Basophils, Week 8, n=216, 293	0.003 (± 0.0204)	0.000 (± 0.0181)		
Basophils, Week 12, n=293, 289	0.002 (± 0.0205)	0.001 (± 0.0197)		
Basophils, Week 16, n=274, 291	0.001 (± 0.0186)	0.001 (± 0.0181)		

Basophils, Week 20, n=273, 291	0.002 (± 0.0225)	0.002 (± 0.0212)		
Basophils, Week 24, n=277, 291	0.002 (± 0.0169)	0.003 (± 0.0167)		
Basophils, Week 28, n=266, 294	0.003 (± 0.0200)	0.002 (± 0.0181)		
Basophils, Week 32, n=262, 282	0.005 (± 0.0199)	0.003 (± 0.0189)		
Basophils, Week 36, n=260, 281	0.009 (± 0.0231)	0.007 (± 0.0217)		
Basophils, Week 40, n=258, 279	0.014 (± 0.0292)	0.011 (± 0.0233)		
Basophils, Week 44, n=258, 267	0.017 (± 0.0283)	0.012 (± 0.0239)		
Basophils, Week 48, n=246, 273	0.019 (± 0.0273)	0.018 (± 0.0263)		
Eosinophils, Week 4, n=299, 290	0.026 (± 0.1394)	0.009 (± 0.1409)		
Eosinophils, Week 8, n=216, 293	0.015 (± 0.1278)	-0.008 (± 0.1319)		
Eosinophils, Week 12, n=293, 289	-0.003 (± 0.1155)	-0.010 (± 0.1533)		
Eosinophils, Week 16, n=274, 291	0.009 (± 0.1246)	-0.011 (± 0.1759)		
Eosinophils, Week 20, n=273, 291	0.009 (± 0.1410)	-0.027 (± 0.1352)		
Eosinophils, Week 24, n=277, 291	0.002 (± 0.1228)	-0.021 (± 0.1490)		
Eosinophils, Week 28, n=266, 294	-0.002 (± 0.1298)	-0.011 (± 0.1387)		
Eosinophils, Week 32, n=262, 282	0.022 (± 0.1629)	-0.012 (± 0.1511)		
Eosinophils, Week 36, n=260, 281	0.002 (± 0.1413)	-0.012 (± 0.1382)		
Eosinophils, Week 40, n=258, 279	0.019 (± 0.1319)	-0.006 (± 0.1283)		
Eosinophils, Week 44, n=258, 267	0.032 (± 0.1388)	-0.004 (± 0.1061)		
Eosinophils, Week 48, n=246, 273	0.032 (± 0.1321)	0.002 (± 0.1253)		
Leukocytes, Week 4, n=300, 297	0.54 (± 1.599)	0.13 (± 1.544)		
Leukocytes, Week 8, n=217, 300	0.19 (± 1.579)	-0.02 (± 1.548)		
Leukocytes, Week 12, n=294, 292	0.35 (± 1.743)	0.10 (± 1.571)		
Leukocytes, Week 16, n=279, 294	0.34 (± 1.653)	0.17 (± 1.558)		
Leukocytes, Week 20, n=276, 297	0.46 (± 1.565)	0.04 (± 1.529)		
Leukocytes, Week 24, n=279, 293	0.32 (± 1.720)	0.10 (± 1.661)		
Leukocytes, Week 28, n=268, 296	0.25 (± 1.651)	0.07 (± 1.471)		
Leukocytes, Week 32, n=267, 287	0.43 (± 1.602)	0.07 (± 1.631)		
Leukocytes, Week 36, n=264, 284	0.33 (± 1.699)	0.13 (± 1.821)		
Leukocytes, Week 40, n=264, 285	0.35 (± 1.808)	0.12 (± 1.675)		
Leukocytes, Week 44, n=269, 278	0.22 (± 1.581)	-0.03 (± 1.561)		
Leukocytes, Week 48, n=252, 281	0.09 (± 1.646)	-0.06 (± 1.538)		
Lymphocytes, Week 4, n=299, 290	0.174 (± 0.5185)	0.128 (± 0.5618)		
Lymphocytes, Week 8, n=216, 293	0.068 (± 0.5319)	0.023 (± 0.5250)		

Lymphocytes, Week 12, n=293, 289	0.033 (± 0.5073)	0.079 (± 0.5844)		
Lymphocytes, Week 16, n=274, 291	0.114 (± 0.5596)	0.095 (± 0.5389)		
Lymphocytes, Week 20, n=273, 291	0.071 (± 0.5274)	0.086 (± 0.5411)		
Lymphocytes, Week 24, n=277, 291	0.079 (± 0.5408)	0.049 (± 0.4863)		
Lymphocytes, Week 28, n=266, 294	0.101 (± 0.6133)	0.069 (± 0.6005)		
Lymphocytes, Week 32, n=262, 282	0.063 (± 0.5392)	0.064 (± 0.5757)		
Lymphocytes, Week 36, n=260, 281	0.008 (± 0.5333)	0.036 (± 0.5525)		
Lymphocytes, Week 40, n=258, 279	0.020 (± 0.5171)	0.035 (± 0.5280)		
Lymphocytes, Week 44, n=258, 267	0.045 (± 0.5430)	0.045 (± 0.5472)		
Lymphocytes, Week 48, n=246, 273	-0.063 (± 0.5528)	-0.035 (± 0.5115)		
Neutrophils, Week 4, n=299, 290	0.258 (± 1.5445)	0.004 (± 1.3601)		
Neutrophils, Week 8, n=216, 293	0.080 (± 1.4401)	-0.031 (± 1.3599)		
Neutrophils, Week 12, n=293, 289	0.283 (± 1.6227)	0.028 (± 1.3884)		
Neutrophils, Week 16, n=274, 291	0.181 (± 1.5415)	0.080 (± 1.4451)		
Neutrophils, Week 20, n=273, 291	0.341 (± 1.4475)	-0.019 (± 1.4228)		
Neutrophils, Week 24, n=277, 291	0.175 (± 1.5883)	0.056 (± 1.5091)		
Neutrophils, Week 28, n=266, 294	0.129 (± 1.4052)	-0.001 (± 1.3377)		
Neutrophils, Week 32, n=262, 282	0.291 (± 1.6015)	0.008 (± 1.4430)		
Neutrophils, Week 36, n=260, 281	0.289 (± 1.5702)	0.077 (± 1.6758)		
Neutrophils, Week 40, n=258, 279	0.245 (± 1.6621)	0.075 (± 1.5336)		
Neutrophils, Week 44, n=258, 267	0.063 (± 1.4874)	-0.105 (± 1.4587)		
Neutrophils, Week 48, n=246, 273	0.009 (± 1.5413)	-0.066 (± 1.3969)		
Monocytes, Week 4, n=299, 290	0.049 (± 0.1663)	0.030 (± 0.1270)		
Monocytes Week 8, n=216, 293	0.014 (± 0.1433)	0.018 (± 0.1591)		
Monocytes, Week 12, n=293, 289	0.018 (± 0.1553)	0.001 (± 0.1367)		
Monocytes, Week 16, n=274, 291	0.005 (± 0.1588)	0.003 (± 0.1403)		
Monocytes, Week 20, n=273, 291	0.003 (± 0.1527)	0.004 (± 0.1328)		
Monocytes, Week 24, n=277, 291	0.012 (± 0.1484)	0.002 (± 0.1331)		
Monocytes, Week 28, n=266, 294	0.001 (± 0.1548)	-0.004 (± 0.1343)		
Monocytes, Week 32, n=262, 282	0.019 (± 0.1535)	0.011 (± 0.1585)		
Monocytes, Week 36, n=260, 281	0.016 (± 0.1501)	0.024 (± 0.1551)		

Monocytes, Week 40, n=258, 279	0.039 (± 0.1507)	0.020 (± 0.1550)		
Monocytes, Week 44, n=258, 267	0.045 (± 0.1673)	0.045 (± 0.1539)		
Monocytes, Week 48, n=246, 273	0.047 (± 0.1502)	0.039 (± 0.1499)		
Platelets, Week 4, n=300, 298	1.8 (± 38.02)	4.3 (± 36.15)		
Platelets, Week 8, n=216, 298	-5.5 (± 31.98)	0.7 (± 35.15)		
Platelets, Week 12, n=294, 290	-0.8 (± 40.83)	5.5 (± 36.76)		
Platelets, Week 16, n=279, 294	-5.2 (± 40.67)	4.3 (± 34.61)		
Platelets, Week 20, n=274, 297	-3.7 (± 36.87)	5.5 (± 38.86)		
Platelets, Week 24, n=279, 292	-4.7 (± 35.22)	6.7 (± 41.78)		
Platelets, Week 28, n=268, 295	-5.3 (± 35.22)	5.4 (± 38.41)		
Platelets, Week 32, n=267, 289	-2.6 (± 36.51)	6.5 (± 35.99)		
Platelets, Week 36, n=267, 284	-1.2 (± 37.26)	9.8 (± 44.52)		
Platelets, Week 40, n=263, 288	0.0 (± 40.74)	9.7 (± 39.91)		
Platelets, Week 44, n=270, 286	4.5 (± 38.31)	9.2 (± 42.82)		
Platelets, Week 48, n=253, 281	0.0 (± 38.63)	10.4 (± 41.75)		

Notes:

[35] - Safety Population

[36] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: erythrocyte mean corpuscular volume

End point title	Change from Baseline for hematology parameters: erythrocyte mean corpuscular volume

End point description:

Blood samples were collected for the analysis of hematology parameter including erythrocyte mean corpuscular volume at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[37]	308[38]		
Units: Femtoliters				
arithmetic mean (standard deviation)				
Week 4, n=300, 300	-1.1 (± 2.71)	0.2 (± 1.82)		
Week 8, n=218, 301	-3.0 (± 4.30)	0.1 (± 1.76)		
Week 12, n=294, 293	-3.9 (± 5.23)	0.2 (± 2.08)		
Week 16, n=280, 296	-4.9 (± 5.86)	0.2 (± 2.42)		
Week 20, n=276, 298	-5.3 (± 5.98)	0.3 (± 2.88)		
Week 24, n=279, 294	-5.4 (± 5.97)	0.3 (± 3.24)		

Week 28, n=268, 297	-5.5 (± 6.11)	0.4 (± 3.46)		
Week 32, n=268, 291	-5.5 (± 6.10)	0.1 (± 3.47)		
Week 36, n=267, 288	-5.8 (± 6.24)	-0.0 (± 3.69)		
Week 40, n=264, 289	-5.6 (± 6.21)	-0.1 (± 3.62)		
Week 44, n=273, 286	-5.8 (± 6.33)	-0.3 (± 3.68)		
Week 48, n=255, 284	-5.7 (± 6.76)	-0.4 (± 3.57)		

Notes:

[37] - Safety Population

[38] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: erythrocytes

End point title	Change from Baseline for hematology parameters: erythrocytes

End point description:

Blood samples were collected for the analysis of hematology parameters including erythrocytes at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[39]	308[40]		
Units: 10^12 cells per liter				
arithmetic mean (standard deviation)				
Week 4, n=300, 300	0.04 (± 0.255)	-0.03 (± 0.226)		
Week 8, n=218, 301	0.14 (± 0.331)	-0.01 (± 0.249)		
Week 12, n=294, 293	0.23 (± 0.374)	0.01 (± 0.252)		
Week 16, n=280, 296	0.28 (± 0.380)	-0.01 (± 0.256)		
Week 20, n=276, 298	0.30 (± 0.408)	-0.01 (± 0.273)		
Week 24, n=279, 294	0.32 (± 0.397)	-0.01 (± 0.246)		
Week 28, n=268, 297	0.28 (± 0.386)	-0.01 (± 0.246)		
Week 32, n=268, 291	0.29 (± 0.393)	-0.01 (± 0.261)		
Week 36, n=267, 288	0.26 (± 0.401)	-0.01 (± 0.259)		
Week 40, n=264, 289	0.27 (± 0.396)	-0.01 (± 0.260)		
Week 44, n=273, 286	0.31 (± 0.391)	-0.01 (± 0.264)		

Week 48, n=255, 284	0.25 (± 0.394)	-0.01 (± 0.262)		

Notes:

[39] - Safety Population

[40] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: hematocrit

End point title	Change from Baseline for hematology parameters: hematocrit

End point description:

Blood samples were collected for the analysis of hematology parameters including hematocrit at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[41]	308[42]		
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Week 4, n=300, 300	-0.0003 (± 0.02236)	-0.0023 (± 0.02194)		
Week 8, n=218, 301	0.0007 (± 0.02613)	-0.0005 (± 0.02330)		
Week 12, n=294, 293	0.0042 (± 0.02607)	0.0020 (± 0.02408)		
Week 16, n=280, 296	0.0038 (± 0.02509)	-0.0007 (± 0.02513)		
Week 20, n=276, 298	0.0043 (± 0.02742)	0.0002 (± 0.02613)		
Week 24, n=279, 294	0.0052 (± 0.02790)	0.0002 (± 0.02576)		
Week 28, n=268, 297	0.0023 (± 0.02699)	0.0002 (± 0.02603)		
Week 32, n=268, 291	0.0022 (± 0.02872)	-0.0011 (± 0.02916)		
Week 36, n=267, 288	-0.0012 (± 0.02793)	-0.0011 (± 0.02797)		
Week 40, n=264, 289	-0.0001 (± 0.02741)	-0.0011 (± 0.02781)		
Week 44, n=273, 286	0.0031 (± 0.02896)	-0.0025 (± 0.02814)		
Week 48, n=255, 284	-0.0021 (± 0.02717)	-0.0031 (± 0.02700)		

Notes:

[41] - Safety Population

[42] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: hemoglobin

End point title	Change from Baseline for hematology parameters: hemoglobin

End point description:

Blood samples were collected for the analysis of hematology parameter including hemoglobin at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[43]	308[44]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Week 4, n=300, 300	-0.4 (± 6.91)	-1.0 (± 6.73)		
Week 8, n=218, 301	-0.4 (± 8.18)	-0.6 (± 7.33)		
Week 12, n=294, 293	0.0 (± 8.14)	-0.3 (± 7.52)		
Week 16, n=280, 296	0.4 (± 8.22)	-1.2 (± 7.75)		
Week 20, n=276, 298	0.3 (± 8.60)	-0.5 (± 8.55)		
Week 24, n=279, 294	1.2 (± 8.78)	-0.0 (± 8.46)		
Week 28, n=268, 297	0.3 (± 8.49)	-0.6 (± 8.68)		
Week 32, n=268, 291	0.9 (± 8.94)	0.2 (± 9.45)		
Week 36, n=267, 288	0.7 (± 9.03)	0.8 (± 9.32)		
Week 40, n=264, 289	0.8 (± 8.96)	0.7 (± 9.29)		
Week 44, n=273, 286	1.7 (± 9.49)	0.6 (± 9.53)		
Week 48, n=255, 284	0.2 (± 9.26)	0.9 (± 9.07)		

Notes:

[43] - Safety Population

[44] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters over time including Week 48: Alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate

aminotransferase (AST) and creatinine kinase (CK)	
End point title	Absolute values for clinical chemistry parameters over time including Week 48: Alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST) and creatinine kinase (CK)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including ALT, ALP, AST and CK at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[45]	308[46]		
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT, Baseline (Day 1), n=308, 308	23.8 (± 13.47)	22.4 (± 12.90)		
ALT, Week 4, n=301, 303	24.4 (± 15.60)	22.3 (± 11.10)		
ALT, Week 8, n=229, 303	24.0 (± 16.85)	24.0 (± 29.86)		
ALT, Week 12, n=295, 299	29.0 (± 114.25)	22.7 (± 13.48)		
ALT, Week 16, n=284, 298	23.7 (± 22.32)	21.8 (± 11.31)		
ALT, Week 20, n=277, 302	23.1 (± 22.49)	21.2 (± 10.50)		
ALT, Week 24, n=284, 299	26.3 (± 62.05)	21.6 (± 12.64)		
ALT, Week 28, n=267, 296	21.1 (± 12.13)	22.1 (± 14.62)		
ALT, Week 32, n=275, 294	21.8 (± 12.56)	21.8 (± 12.09)		
ALT, Week 36, n=273, 292	23.2 (± 24.94)	22.3 (± 12.17)		
ALT, Week 40, n=270, 293	24.5 (± 37.39)	22.1 (± 12.78)		
ALT, Week 44, n=275, 293	21.6 (± 13.10)	22.1 (± 13.67)		
ALT, Week 48, n=265, 292	21.8 (± 13.54)	21.7 (± 11.08)		
ALP, Baseline (Day 1), n=308, 308	76.6 (± 28.20)	77.5 (± 26.77)		
ALP, Week 4, n=301, 303	70.4 (± 22.75)	75.7 (± 25.58)		
ALP, Week 8, n=229, 303	68.9 (± 21.98)	78.8 (± 32.40)		
ALP, Week 12, n=295, 299	68.9 (± 24.79)	78.6 (± 28.87)		
ALP, Week 16, n=284, 298	67.9 (± 19.76)	77.3 (± 27.21)		
ALP, Week 20, n=277, 302	67.6 (± 18.72)	76.7 (± 25.48)		
ALP, Week 24, n=284, 299	68.1 (± 19.15)	77.5 (± 26.36)		
ALP, Week 28, n=267, 296	67.6 (± 18.89)	77.2 (± 26.72)		
ALP, Week 32, n=275, 294	66.6 (± 19.14)	75.8 (± 25.56)		
ALP, Week 36, n=273, 292	66.8 (± 20.68)	76.4 (± 25.93)		
ALP, Week 40, n=270, 293	66.2 (± 17.58)	76.2 (± 26.08)		
ALP, Week 44, n=275, 293	66.1 (± 18.34)	76.8 (± 25.82)		
ALP, Week 48, n=265, 292	66.5 (± 18.84)	77.1 (± 26.39)		
AST, Baseline (Day 1), n=308, 308	23.9 (± 11.31)	22.5 (± 10.21)		
AST, Week 4, n=301, 303	23.2 (± 11.77)	22.7 (± 10.93)		
AST, Week 8, n=229, 303	24.3 (± 19.49)	22.5 (± 12.31)		
AST, Week 12, n=295, 299	26.1 (± 64.69)	23.2 (± 10.61)		
AST, Week 16, n=284, 298	24.1 (± 18.20)	22.5 (± 8.59)		

AST, Week 20, n=277, 302	23.5 (± 15.23)	22.0 (± 6.83)		
AST, Week 24, n=284, 298	24.2 (± 22.89)	22.5 (± 9.30)		
AST, Week 28, n=267, 296	22.2 (± 8.72)	22.9 (± 9.61)		
AST, Week 32, n=275, 294	22.8 (± 13.71)	23.2 (± 12.32)		
AST, Week 36, n=273, 292	23.0 (± 11.27)	22.6 (± 7.18)		
AST, Week 40, n=270, 293	23.8 (± 14.96)	22.5 (± 7.79)		
AST, Week 44, n=275, 293	22.9 (± 14.82)	22.6 (± 10.26)		
AST Week 48, n=265, 292	22.9 (± 10.35)	23.2 (± 9.30)		
CK, Baseline (Day 1), n=308, 308	196.6 (± 367.30)	160.8 (± 367.57)		
CK, Week 4, n=301, 303	192.9 (± 437.09)	190.6 (± 472.57)		
CK, Week 8, n=229, 303	275.9 (± 1064.72)	145.4 (± 141.19)		
CK, Week 12, n=295, 299	200.7 (± 484.08)	177.0 (± 321.29)		
CK, Week 16, n=284, 298	253.5 (± 849.45)	167.5 (± 286.90)		
CK, Week 20, n=277, 302	228.4 (± 570.80)	144.5 (± 133.32)		
CK, Week 24, n=284, 299	193.1 (± 444.27)	161.2 (± 241.73)		
CK, Week 28, n=267, 296	168.8 (± 163.54)	182.7 (± 420.44)		
CK, Week 32, n=275, 294	216.5 (± 593.10)	195.9 (± 489.99)		
CK, Week 36, n=273, 292	186.4 (± 325.64)	150.7 (± 134.40)		
CK, Week 40, n=270, 293	235.1 (± 624.03)	160.7 (± 179.64)		
CK, Week 44, n=275, 293	245.5 (± 1189.35)	149.9 (± 148.23)		
CK, Week 48, n=265, 292	198.8 (± 398.14)	179.0 (± 331.51)		

Notes:

[45] - Safety Population

[46] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameter over time including Week 48: Albumin

End point title	Absolute values for clinical chemistry parameter over time including Week 48: Albumin

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-albumin at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[47]	308[48]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=308, 308	44.2 (± 3.12)	44.3 (± 3.19)		
Week 4, n=301, 303	43.7 (± 2.88)	43.8 (± 2.87)		
Week 8, n=229, 303	43.8 (± 3.06)	43.7 (± 3.17)		
Week 12, n=295, 299	43.6 (± 2.99)	43.9 (± 3.12)		
Week 16, n=284, 298	43.5 (± 2.77)	43.5 (± 3.12)		
Week 20, n=277, 302	43.4 (± 2.72)	43.5 (± 3.07)		
Week 24, n=284, 299	43.4 (± 2.74)	43.5 (± 3.02)		
Week 28, n=267, 296	43.6 (± 2.85)	43.3 (± 3.07)		
Week 32, n=275, 294	43.5 (± 2.83)	43.4 (± 3.25)		
Week 36, n=273, 292	43.3 (± 2.82)	43.4 (± 3.07)		
Week 40, n=270, 293	43.7 (± 2.72)	43.4 (± 3.04)		
Week 44, n=275, 293	43.7 (± 2.78)	43.5 (± 3.02)		
Week 48, n=265, 292	43.8 (± 2.74)	44.0 (± 2.92)		

Notes:

[47] - Safety Population

[48] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters over time including Week 48: bilirubin, direct bilirubin and creatinine

End point title	Absolute values for clinical chemistry parameters over time including Week 48: bilirubin, direct bilirubin and creatinine

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including bilirubin, creatinine and direct bilirubin at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[49]	308[50]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin, Baseline (Day 1), n=308, 308	9.9 (± 9.71)	9.2 (± 6.39)		
Bilirubin, Week 4, n=301, 303	9.1 (± 3.98)	8.9 (± 6.14)		
Bilirubin, Week 8, n=229, 303	9.3 (± 4.05)	9.4 (± 9.06)		
Bilirubin, Week 12, n=295, 299	9.3 (± 4.45)	9.3 (± 6.62)		
Bilirubin, Week 16, n=284, 298	10.0 (± 10.71)	9.1 (± 6.28)		
Bilirubin, Week 20, n=277, 302	9.7 (± 4.28)	9.3 (± 7.56)		

Bilirubin, Week 24, n=284, 298	9.3 (± 3.90)	9.4 (± 8.38)		
Bilirubin, Week 28, n=267, 296	9.8 (± 3.99)	9.1 (± 7.05)		
Bilirubin, Week 32, n=275, 294	9.8 (± 4.36)	9.3 (± 7.05)		
Bilirubin, Week 36, n=273, 292	9.3 (± 3.79)	9.2 (± 7.34)		
Bilirubin, Week 40, n=270, 293	9.6 (± 4.07)	9.5 (± 9.04)		
Bilirubin, Week 44, n=275, 293	9.6 (± 4.19)	9.7 (± 8.49)		
Bilirubin, Week 48, n=265, 292	9.7 (± 4.24)	9.5 (± 6.36)		
Direct bilirubin, Baseline (Day 1), n=308, 308	2.4 (± 1.35)	2.2 (± 1.25)		
Direct bilirubin, Week 4, n=301, 303	2.3 (± 1.04)	2.3 (± 1.27)		
Direct bilirubin, Week 8, n=229, 303	2.3 (± 1.08)	2.4 (± 3.96)		
Direct bilirubin, Week 12, n=295, 299	2.2 (± 1.03)	2.3 (± 1.30)		
Direct bilirubin, Week 16, n=284, 298	2.5 (± 4.98)	2.1 (± 1.08)		
Direct bilirubin, Week 20, n=277, 302	2.2 (± 0.95)	2.0 (± 1.31)		
Direct bilirubin, Week 24, n=284, 298	2.2 (± 0.99)	2.1 (± 1.26)		
Direct bilirubin, Week 28, n=267, 296	2.1 (± 0.94)	2.0 (± 1.28)		
Direct bilirubin, Week 32, n=275, 294	2.1 (± 1.00)	2.0 (± 1.22)		
Direct bilirubin, Week 36, n=273, 292	2.1 (± 1.11)	2.1 (± 1.27)		
Direct bilirubin, Week 40, n=270, 293	2.1 (± 1.08)	2.1 (± 1.37)		
Direct bilirubin, Week 44, n=275, 293	2.2 (± 0.95)	2.2 (± 1.30)		
Direct bilirubin, Week 48, n=265, 292	2.2 (± 0.92)	2.2 (± 1.23)		
Creatinine, Baseline (Day 1), n=308, 308	79.05 (± 16.380)	77.83 (± 16.497)		
Creatinine, Week 4, n=301, 301	80.17 (± 15.464)	79.47 (± 16.284)		
Creatinine, Week 8, n=229, 303	78.79 (± 16.122)	79.22 (± 16.824)		
Creatinine, Week 12, n=295, 299	78.65 (± 16.534)	79.50 (± 17.191)		
Creatinine, Week 16, n=284, 298	78.72 (± 15.606)	79.51 (± 17.171)		
Creatinine, Week 20, n=277, 302	79.75 (± 15.695)	79.62 (± 16.909)		
Creatinine, Week 24, n=284, 298	80.15 (± 18.478)	79.05 (± 16.673)		
Creatinine, Week 28, n=267, 296	80.42 (± 16.335)	79.35 (± 16.574)		
Creatinine, Week 32, n=275, 294	79.65 (± 15.044)	79.69 (± 16.634)		
Creatinine, Week 36, n=273, 292	79.73 (± 15.994)	79.34 (± 16.527)		
Creatinine, Week 40, n=270, 293	80.28 (± 15.856)	79.42 (± 16.856)		
Creatinine, Week 44, n=275, 293	79.98 (± 15.775)	79.16 (± 16.583)		
Creatinine, Week 48, n=265, 292	80.77 (± 16.456)	78.65 (± 16.204)		

Notes:

[49] - Safety Population

[50] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters: total carbon-dioxide (CO2), chloride, glucose, phosphate, potassium, sodium and urea over time

including Week 48

End point title	Absolute values for clinical chemistry parameters: total carbon-dioxide (CO2), chloride, glucose, phosphate, potassium, sodium and urea over time including Week 48

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters which includes total CO2, chloride, glucose, phosphate, potassium, sodium and urea at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[51]	308[52]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
CO2, Baseline (Day 1), n=308, 308	22.7 (± 2.33)	22.6 (± 2.24)		
CO2, Week 4, n=301, 303	23.7 (± 2.49)	23.3 (± 2.27)		
CO2, Week 8, n=229, 303	23.1 (± 2.17)	23.2 (± 2.47)		
CO2, Week 12, n=295, 299	23.2 (± 2.14)	23.0 (± 2.36)		
CO2, Week 16, n=284, 298	22.9 (± 2.16)	23.0 (± 2.31)		
CO2, Week 20, n=277, 302	22.9 (± 2.16)	22.9 (± 2.29)		
CO2, Week 24, n=284, 298	22.9 (± 2.31)	22.8 (± 2.41)		
CO2, Week 28, n=267, 296	22.7 (± 2.42)	22.7 (± 2.27)		
CO2, Week 32, n=275, 294	22.6 (± 2.15)	22.8 (± 2.34)		
CO2, Week 36, n=273, 292	22.8 (± 2.19)	23.0 (± 2.26)		
CO2, Week 40, n=270, 293	23.1 (± 2.27)	23.0 (± 2.45)		
CO2, Week 44, n=275, 293	23.0 (± 2.19)	23.2 (± 2.31)		
CO2, Week 48, n=265, 292	22.7 (± 2.29)	22.9 (± 2.29)		
Chloride, Baseline (Day 1), n=308, 308	103.8 (± 2.03)	103.8 (± 2.39)		
Chloride, Week 4, n=301, 303	104.3 (± 2.13)	104.3 (± 2.22)		
Chloride, Week 8, n=229, 303	104.3 (± 2.26)	104.2 (± 2.40)		
Chloride, Week 12, n=295, 299	104.2 (± 2.27)	104.3 (± 2.24)		
Chloride, Week 16, n=284, 298	104.5 (± 2.21)	104.5 (± 2.28)		
Chloride, Week 20, n=277, 302	104.7 (± 2.41)	104.5 (± 2.38)		
Chloride, Week 24, n=284, 299	104.5 (± 2.36)	104.7 (± 2.30)		
Chloride, Week 28, n=267, 296	104.8 (± 2.19)	104.8 (± 2.36)		
Chloride, Week 32, n=275, 294	104.7 (± 2.50)	104.7 (± 2.31)		
Chloride, Week 36, n=273, 292	104.8 (± 2.18)	104.6 (± 2.36)		
Chloride, Week 40, n=270, 293	104.7 (± 2.22)	104.6 (± 2.61)		
Chloride, Week 44, n=275, 293	104.6 (± 2.10)	104.6 (± 2.27)		
Chloride, Week 48, n=265, 292	104.4 (± 2.38)	104.1 (± 2.37)		
Glucose, Baseline (Day 1), n=301, 299	5.00 (± 0.714)	5.17 (± 0.988)		
Glucose, Week 4, n=216, 226	5.17 (± 0.747)	5.42 (± 1.250)		
Glucose, Week 8, n=153, 218	5.16 (± 0.990)	5.35 (± 1.037)		
Glucose, Week 12, n=206, 221	5.19 (± 0.965)	5.35 (± 1.091)		
Glucose, Week 16, n=209, 216	5.22 (± 1.163)	5.36 (± 1.317)		

Glucose, Week 20, n=194, 221	5.20 (± 0.736)	5.37 (± 1.209)		
Glucose, Week 24, n=215, 229	5.24 (± 0.810)	5.35 (± 0.840)		
Glucose, Week 28, n=190, 226	5.16 (± 0.697)	5.36 (± 0.876)		
Glucose, Week 32, n=194, 219	5.33 (± 1.042)	5.45 (± 1.102)		
Glucose, Week 36, n=191, 220	5.19 (± 0.777)	5.40 (± 1.507)		
Glucose, Week 40, n=195, 218	5.30 (± 0.797)	5.44 (± 1.227)		
Glucose, Week 44, n=193, 213	5.22 (± 0.887)	5.44 (± 1.317)		
Glucose, Week 48, n=242, 277	5.08 (± 0.614)	5.22 (± 0.963)		
Phosphate, Baseline (Day 1), n=308, 308	1.042 (± 0.1771)	1.051 (± 0.1722)		
Phosphate, Week 4, n=301, 303	1.110 (± 0.1793)	1.066 (± 0.1773)		
Phosphate, Week 8, n=229, 303	1.097 (± 0.1944)	1.042 (± 0.1843)		
Phosphate, Week 12, n=295, 299	1.080 (± 0.1872)	1.062 (± 0.1922)		
Phosphate, Week 16, n=284, 298	1.081 (± 0.1796)	1.052 (± 0.1724)		
Phosphate, Week 20, n=277, 302	1.073 (± 0.1746)	1.061 (± 0.1873)		
Phosphate, Week 24, n=284, 299	1.082 (± 0.1788)	1.057 (± 0.1849)		
Phosphate, Week 28, n=267, 296	1.072 (± 0.1714)	1.053 (± 0.1741)		
Phosphate, Week 32, n=275, 294	1.061 (± 0.1730)	1.054 (± 0.1761)		
Phosphate, Week 36, n=273, 292	1.052 (± 0.1700)	1.049 (± 0.1798)		
Phosphate, Week 40, n=270, 293	1.065 (± 0.1789)	1.046 (± 0.1763)		
Phosphate, Week 44, n=275, 293	1.066 (± 0.1798)	1.052 (± 0.1902)		
Phosphate, Week 48, n=265, 292	1.077 (± 0.1816)	1.052 (± 0.1834)		
Potassium, Baseline (Day 1), n=308, 308	4.16 (± 0.281)	4.17 (± 0.314)		
Potassium, Week 4, n=301, 303	4.21 (± 0.307)	4.28 (± 0.352)		
Potassium, Week 8, n=229, 303	4.16 (± 0.296)	4.22 (± 0.393)		
Potassium, Week 12, n=295, 299	4.19 (± 0.330)	4.24 (± 0.332)		
Potassium, Week 16, n=284, 298	4.18 (± 0.316)	4.23 (± 0.321)		
Potassium, Week 20, n=277, 302	4.19 (± 0.311)	4.21 (± 0.320)		
Potassium, Week 24, n=284, 298	4.18 (± 0.287)	4.23 (± 0.337)		
Potassium, Week 28, n=267, 296	4.19 (± 0.346)	4.24 (± 0.391)		
Potassium, Week 32, n=275, 294	4.18 (± 0.368)	4.21 (± 0.341)		
Potassium, Week 36, n=273, 292	4.19 (± 0.326)	4.23 (± 0.345)		
Potassium, Week 40, n=270, 293	4.20 (± 0.301)	4.23 (± 0.322)		
Potassium, Week 44, n=275, 293	4.21 (± 0.323)	4.23 (± 0.359)		
Potassium, Week 48, n=265, 292	4.15 (± 0.271)	4.16 (± 0.331)		
Sodium, Baseline (Day 1), n=308, 308	139.0 (± 1.91)	139.0 (± 1.76)		
Sodium, Week 4, n=301, 303	139.3 (± 1.70)	139.1 (± 1.87)		
Sodium, Week 8, n=229, 303	139.1 (± 1.98)	139.0 (± 1.80)		
Sodium, Week 12, n=295, 299	139.2 (± 1.84)	139.2 (± 1.85)		
Sodium, Week 16, n=284, 298	139.1 (± 1.98)	139.1 (± 1.96)		
Sodium, Week 20, n=277, 302	139.2 (± 1.87)	139.3 (± 1.81)		
Sodium, Week 24, n=284, 299	139.3 (± 1.88)	139.3 (± 1.96)		
Sodium, Week 28, n=267, 296	139.5 (± 1.77)	139.2 (± 2.01)		

Sodium, Week 32, n=275, 294	139.3 (± 1.75)	139.5 (± 1.84)		
Sodium, Week 36, n=273, 292	139.4 (± 1.79)	139.5 (± 2.15)		
Sodium, Week 40, n=270, 293	139.4 (± 1.93)	139.5 (± 1.97)		
Sodium, Week 44, n=275, 293	139.4 (± 1.80)	139.5 (± 1.93)		
Sodium, Week 48, n=265, 292	139.4 (± 1.94)	139.4 (± 1.83)		
Urea, Baseline (Day 1), n=308, 308	5.23 (± 1.546)	5.22 (± 1.632)		
Urea, Week 4, n=301, 303	5.24 (± 1.495)	5.28 (± 1.549)		
Urea, Week 8, n=229, 303	5.32 (± 1.640)	5.22 (± 1.529)		
Urea, Week 12, n=295, 299	5.38 (± 1.612)	5.30 (± 1.649)		
Urea, Week 16, n=284, 298	5.30 (± 1.662)	5.41 (± 1.659)		
Urea, Week 20, n=277, 302	5.37 (± 1.631)	5.33 (± 1.662)		
Urea, Week 24, n=284, 299	5.49 (± 1.749)	5.36 (± 1.639)		
Urea, Week 28, n=267, 296	5.39 (± 1.756)	5.24 (± 1.527)		
Urea, Week 32, n=275, 294	5.44 (± 1.624)	5.29 (± 1.599)		
Urea, Week 36, n=273, 292	5.26 (± 1.664)	5.20 (± 1.485)		
Urea, Week 40, n=270, 293	5.47 (± 1.593)	5.30 (± 1.537)		
Urea, Week 44, n=275, 293	5.37 (± 1.531)	5.26 (± 1.524)		
Urea, Week 48, n=265, 292	5.48 (± 1.648)	5.21 (± 1.437)		

Notes:

[51] - Safety Population

[52] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameter over time including Week 48: Lipase

End point title	Absolute values for clinical chemistry parameter over time including Week 48: Lipase

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-lipase at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[53]	308[54]		
Units: Units per liter				
arithmetic mean (standard deviation)				
Baseline, n=308, 308	30.5 (± 22.88)	30.8 (± 19.12)		
Week 4, n=301, 303	35.3 (± 52.73)	32.3 (± 23.30)		
Week 8, n=227, 303	30.6 (± 22.70)	31.9 (± 20.71)		
Week 12, n=294, 297	33.2 (± 27.92)	30.0 (± 18.06)		
Week 16, n=285, 299	33.8 (± 30.49)	33.9 (± 34.69)		
Week 20, n=278, 302	31.0 (± 21.73)	31.6 (± 28.88)		

Week 24, n=283, 299	33.1 (± 24.09)	33.8 (± 29.69)		
Week 28, n=267, 297	32.9 (± 27.42)	33.1 (± 19.69)		
Week 32, n=274, 294	35.7 (± 60.63)	33.8 (± 21.64)		
Week 36, n=273, 292	36.2 (± 51.58)	31.6 (± 18.46)		
Week 40, n=269, 293	35.7 (± 36.06)	31.4 (± 15.80)		
Week 44, n=274, 293	33.3 (± 26.29)	33.3 (± 20.44)		
Week 48, n=264, 290	34.3 (± 30.97)	32.4 (± 20.40)		

Notes:

[53] - Safety Population

[54] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameter over time including Week 48: Creatinine clearance

End point title	Absolute values for clinical chemistry parameter over time including Week 48: Creatinine clearance

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-creatinine clearance at indicated timepoints. Glomerular filtration rate (GFR) was estimated by the central laboratory using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[55]	308[56]		
Units: Milliliter per minute per 1.73meter^2				
arithmetic mean (standard deviation)				
Baseline, n=308, 308	100.5 (± 18.30)	101.1 (± 17.72)		
Week 4, n=301, 301	98.7 (± 17.26)	98.9 (± 17.93)		
Week 8, n=227, 303	100.1 (± 17.19)	99.5 (± 17.59)		
Week 12, n=295, 297	100.9 (± 17.72)	99.2 (± 18.34)		
Week 16, n=284, 297	100.5 (± 17.26)	99.0 (± 18.32)		
Week 20, n=277, 302	99.4 (± 17.37)	98.7 (± 17.73)		
Week 24, n=283, 298	98.9 (± 17.04)	98.9 (± 17.44)		
Week 28, n=267, 296	98.5 (± 17.66)	99.0 (± 17.33)		
Week 32, n=274, 294	99.1 (± 16.89)	98.4 (± 17.54)		
Week 36, n=273, 292	99.0 (± 17.19)	98.6 (± 16.85)		
Week 40, n=268, 293	98.5 (± 17.32)	98.5 (± 17.37)		
Week 44, n=274, 293	98.2 (± 16.96)	99.0 (± 17.39)		
Week 48, n=264, 291	97.6 (± 16.97)	99.3 (± 17.09)		

Notes:

[55] - Safety Population

[56] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal urinalysis parameters over time including Week 48

End point title	Number of participants with abnormal urinalysis parameters over time including Week 48

End point description:

The dipstick test gives results in a semi-quantitative manner and results for urinalysis parameters (ketones, glucose, bilirubin, occult blood, nitrite and blood protein) can be read as positive, trace, 1+, 2+, 3+ and 4+ indicating proportional concentrations in the urine sample. The urine parameters were graded according to Division of AIDS (DAIDS) scale where Grade 1 indicates mild (trace to 1+), Grade 2 indicates moderate (2+) and Grade 3 indicates severe (3+ or higher). Only participants with abnormal findings for urinalysis at any visit has been presented. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48.

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[57]	308[58]		
Units: Participants				
Urine bilirubin,Baseline (Day 1),Trace, n=303, 301	0	0		
Urine bilirubin, Baseline (Day 1), 1+, n=303, 301	6	7		
Urine bilirubin, Baseline (Day 1), 2+, n=303, 301	0	0		
Urine bilirubin, Baseline (Day 1), 3+, n=303, 301	0	0		
Urine glucose, Baseline (Day 1), Trace, n=303, 301	1	1		
Urine glucose, Baseline (Day 1), 1+, n=303, 301	0	1		
Urine glucose, Baseline (Day 1), 2+, n=303, 301	0	0		
Urine glucose, Baseline (Day 1), 3+, n=303, 301	0	1		
Urine ketones, Baseline (Day 1), Trace, n=303, 301	16	17		
Urine ketones, Baseline (Day 1), 1+, n=303, 301	4	0		
Urine ketones, Baseline (Day 1), 2+, n=303, 301	2	1		
Urine ketones, Baseline (Day 1), 3+, n=303, 301	0	0		

Urine leukocyte esterase,Baseline,Trace,n=303,301	25	18		
Urine leukocyte esterase, Baseline, 1+, n=303, 301	14	16		
Urine leukocyte esterase, Baseline, 2+, n=303, 301	14	8		
Urine leukocyte esterase, Baseline, 3+, n=303, 301	5	5		
Urine nitrite, Baseline, positive, n=303, 301	11	11		
Urine occult blood, Baseline, Trace, n=303, 301	19	12		
Urine occult blood, Baseline, 1+, n=303, 301	8	9		
Urine occult blood, Baseline, 2+, n=303, 301	7	5		
Urine occult blood, Baseline, 3+, n=303, 301	5	3		
Urine protein, Baseline, Trace, n=303, 301	14	20		
Urine protein, Baseline, 1+, n=303, 301	6	12		
Urine protein, Baseline, 2+, n=303, 301	0	1		
Urine protein, Baseline, 3+, n=303, 301	0	0		
Urine protein, Baseline, 4+, n=303, 301	0	0		
Urine bilirubin, Week 4, Trace, n=303, 302	0	0		
Urine bilirubin, Week 4, 1+, n=303, 302	9	5		
Urine bilirubin, Week 4, 2+, n=303, 302	0	0		
Urine bilirubin, Week 4, 3+, n=303, 302	0	0		
Urine glucose, Week 4, Trace, n=303, 302	3	2		
Urine glucose, Week 4, 1+, n=303, 302	1	2		
Urine glucose, Week 4, 2+, n=303, 302	2	0		
Urine glucose, Week 4, 3+, n=303, 302	0	1		
Urine ketones, Week 4, Trace, n=303, 302	9	15		
Urine ketones, Week 4, 1+, n=303, 302	0	2		
Urine ketones, Week 4, 2+, n=303, 302	1	1		
Urine ketones, Week 4, 3+, n=303, 302	0	0		
Urine leukocyte esterase, Week 4, Trace,n=303, 302	25	29		
Urine leukocyte esterase, Week 4, 1+, n=303, 302	14	15		
Urine leukocyte esterase, Week 4, 2+, n=303, 302	14	9		
Urine leukocyte esterase, Week 4, 3+, n=303, 302	3	4		
Urine nitrite, Week 4, positive, n=303, 302	10	12		
Urine occult blood, Week 4, Trace, n=303, 302	15	18		
Urine occult blood, Week 4, 1+, n=303, 302	9	10		
Urine occult blood, Week 4, 2+, n=303, 302	5	5		
Urine occult blood, Week 4, 3+, n=303, 302	4	3		
Urine protein, Week 4, Trace, n=303, 302	10	13		

Urine protein, Week 4, 1+, n=303, 302	8	7		
Urine protein, Week 4, 2+, n=303, 302	2	4		
Urine protein, Week 4, 3+, n=303, 302	0	0		
Urine protein, Week 4, 4+, n=303, 302	0	0		
Urine bilirubin, Week 24, Trace, n=279, 298	0	0		
Urine bilirubin, Week 24, 1+, n=279, 298	10	13		
Urine bilirubin, Week 24, 2+, n=279, 298	0	0		
Urine bilirubin, Week 24, 3+, n=279, 298	0	0		
Urine glucose, Week 24, Trace, n=279, 298	0	1		
Urine glucose, Week 24, 1+, n=279, 298	2	0		
Urine glucose, Week 24, 2+, n=279, 298	0	1		
Urine glucose, Week 24, 3+, n=279, 298	1	1		
Urine ketones, Week 24, Trace, n=279, 298	16	13		
Urine ketones, Week 24, 1+, n=279, 298	1	1		
Urine ketones, Week 24, 2+, n=279, 298	0	0		
Urine ketones, Week 24, 3+, n=279, 298	0	0		
Urine leukocyte esterase,Week 24, Trace, n=279,298	22	17		
Urine leukocyte esterase, Week 24, 1+, n=279, 298	14	14		
Urine leukocyte esterase, Week 24, 2+, n=279, 298	6	14		
Urine leukocyte esterase, Week 24, 3+, n=279, 298	3	7		
Urine nitrite, Week 24, positive, n=279, 298	9	10		
Urine occult blood, Week 24, Trace, n=279, 298	13	10		
Urine occult blood, Week 24, 1+, n=279, 298	5	6		
Urine occult blood, Week 24, 2+, n=279, 298	6	4		
Urine occult blood, Week 24, 3+, n=279, 298	0	6		
Urine protein, Week 24, Trace, n=279, 298	10	21		
Urine protein, Week 24, 1+, n=279, 298	4	12		
Urine protein, Week 24, 2+, n=279, 298	1	3		
Urine protein, Week 24, 3+, n=279, 298	0	0		
Urine protein, Week 24, 4+, n=279, 298	0	0		
Urine bilirubin, Week 48, Trace, n=279, 290	0	0		
Urine bilirubin, Week 48, 1+, n=279, 290	9	8		
Urine bilirubin, Week 48, 2+, n=279, 290	1	0		
Urine bilirubin, Week 48, 3+, n=279, 290	0	0		

Urine glucose, Week 48, Trace, n=279, 290	0	1		
Urine glucose, Week 48, 1+, n=279, 290	0	2		
Urine glucose, Week 48, 2+, n=279, 290	1	0		
Urine glucose, Week 48, 3+, n=279, 290	0	2		
Urine ketones, Week 48, Trace, n=279, 290	13	9		
Urine ketones, Week 48, 1+, n=279, 290	0	0		
Urine ketones, Week 48, 2+, n=279, 290	0	0		
Urine ketones, Week 48, 3+, n=279, 290	0	0		
Urine leukocyte esterase, Week 48, Trace,n=279,290	24	27		
Urine leukocyte esterase, Week 48, 1+, n=279, 290	13	15		
Urine leukocyte esterase, Week 48, 2+, n=279, 290	7	7		
Urine leukocyte esterase, Week 48, 3+, n=279, 290	5	6		
Urine nitrite, Week 48, positive, n=279, 290	10	6		
Urine occult blood, Week 48, Trace, n=279, 290	11	12		
Urine occult blood, Week 48, 1+, n=279, 290	5	5		
Urine occult blood, Week 48, 2+, n=279, 290	4	4		
Urine occult blood, Week 48, 3+, n=279, 290	6	0		
Urine protein, Week 48, Trace, n=279, 290	10	15		
Urine protein, Week 48, 1+, n=279, 290	4	6		
Urine protein, Week 48, 2+, n=279, 290	3	3		
Urine protein, Week 48, 3+, n=279, 290	0	0		
Urine protein, Week 48, 4+, n=279, 290	0	1		

Notes:

[57] - Safety Population

[58] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with urine potential of hydrogen (pH) over time including Week 48

End point title	Number of participants with urine potential of hydrogen (pH) over time including Week 48

End point description:

Urine samples were collected for analysis of urine pH. pH is calculated on a scale of 0 to 14, values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH of less than 7 is acidic and a pH of greater than 7 is basic. Normal urine has a slightly acidic pH (5.0-6.0). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:
Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[59]	308[60]		
Units: Participants				
Baseline, pH=5, n=303, 301	44	42		
Baseline, pH=5.5, n=303, 301	78	80		
Baseline, pH=6, n=303, 301	85	72		
Baseline, pH=6.5, n=303, 301	47	45		
Baseline, pH=7, n=303, 301	32	34		
Baseline, pH=7.5, n=303, 301	12	19		
Baseline, pH=8, n=303, 301	3	7		
Baseline, pH=8.5, n=303, 301	0	1		
Baseline, pH>9.0, n=303, 301	2	1		
Week 4, pH=5, n=303, 302	41	53		
Week 4, pH=5.5, n=303, 302	78	93		
Week 4, pH=6, n=303, 302	73	67		
Week 4, pH=6.5, n=303, 302	49	41		
Week 4, pH=7, n=303, 302	38	28		
Week 4, pH=7.5, n=303, 302	12	14		
Week 4, pH=8, n=303, 302	8	3		
Week 4, pH=8.5, n=303, 302	3	2		
Week 4, pH>9.0, n=303, 302	1	1		
Week 24, pH=5, n=279, 298	23	26		
Week 24, pH=5.5, n=279, 298	85	96		
Week 24, pH=6, n=279, 298	66	67		
Week 24, pH=6.5, n=279, 298	44	52		
Week 24, pH=7, n=279, 298	32	31		
Week 24, pH=7.5, n=279, 298	16	15		
Week 24, pH=8, n=279, 298	7	8		
Week 24, pH=8.5, n=279, 298	2	2		
Week 24, pH>9.0, n=279, 298	4	1		
Week 48, pH=5, n=279, 290	45	43		
Week 48, pH=5.5, n=279, 290	69	83		
Week 48, pH=6, n=279, 290	61	58		
Week 48, pH=6.5, n=279, 290	47	48		
Week 48, pH=7, n=279, 290	31	30		
Week 48, pH=7.5, n=279, 290	17	17		
Week 48, pH=8, n=279, 290	6	5		
Week 48, pH=8.5, n=279, 290	0	4		
Week 48, pH>9.0, n=279, 290	3	2		

Notes:
[59] - Safety Population
[60] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters over time including Week 48: ALT, ALP, AST and CK

End point title	Change from Baseline in clinical chemistry parameters over time including Week 48: ALT, ALP, AST and CK

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including ALT, ALP, AST and CK. Baseline values is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[61]	308[62]		
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT, Week 4, n=301, 303	0.8 (± 13.98)	0.1 (± 9.65)		
ALT, Week 8, n=229, 303	0.7 (± 15.35)	1.6 (± 29.98)		
ALT, Week 12, n=295, 299	5.2 (± 113.34)	0.4 (± 11.60)		
ALT, Week 16, n=284, 298	-0.1 (± 21.80)	-0.6 (± 10.14)		
ALT, Week 20, n=277, 302	-0.8 (± 22.62)	-1.1 (± 10.86)		
ALT, Week 24, n=284, 299	2.2 (± 61.65)	-0.6 (± 10.57)		
ALT, Week 28, n=267, 296	-2.7 (± 11.14)	-0.2 (± 12.52)		
ALT, Week 32, n=275, 294	-1.9 (± 14.44)	-0.5 (± 11.49)		
ALT, Week 36, n=273, 292	-0.8 (± 23.51)	0.1 (± 10.95)		
ALT, Week 40, n=270, 293	0.6 (± 36.29)	-0.2 (± 11.82)		
ALT, Week 44, n=275, 293	-2.2 (± 13.97)	-0.2 (± 12.37)		
ALT, Week 48, n=265, 292	-1.9 (± 13.43)	-0.6 (± 10.50)		
ALP, Week 4, n=301, 303	-6.0 (± 12.74)	-2.2 (± 8.85)		
ALP, Week 8, n=229, 303	-6.7 (± 16.59)	1.1 (± 20.99)		
ALP, Week 12, n=295, 299	-8.0 (± 20.87)	0.9 (± 14.45)		
ALP, Week 16, n=284, 298	-9.7 (± 19.47)	-0.5 (± 10.35)		
ALP, Week 20, n=277, 302	-9.2 (± 19.05)	-1.0 (± 11.65)		
ALP, Week 24, n=284, 299	-9.0 (± 19.02)	-0.1 (± 10.67)		
ALP, Week 28, n=267, 296	-10.1 (± 19.08)	-0.2 (± 11.44)		
ALP, Week 32, n=275, 294	-9.9 (± 19.10)	-1.7 (± 11.29)		
ALP, Week 36, n=273, 292	-10.5 (± 20.41)	-1.1 (± 11.44)		
ALP, Week 40, n=270, 293	-10.4 (± 20.71)	-1.1 (± 11.34)		
ALP, Week 44, n=275, 293	-11.4 (± 20.64)	-0.7 (± 12.02)		
ALP, Week 48, n=265, 292	-10.9 (± 23.27)	-0.3 (± 12.51)		
AST, Week 4, n=301, 303	-0.3 (± 12.52)	0.2 (± 10.02)		

AST, Week 8, n=229, 303	1.2 (± 19.73)	-0.1 (± 13.68)		
AST, Week 12, n=295, 299	2.3 (± 65.03)	0.6 (± 8.82)		
AST, Week 16, n=284, 298	0.1 (± 18.49)	-0.1 (± 9.71)		
AST, Week 20, n=277, 302	-0.5 (± 17.02)	-0.6 (± 9.80)		
AST, Week 24, n=284, 298	0.1 (± 24.12)	0.0 (± 9.57)		
AST, Week 28, n=267, 296	-1.4 (± 8.77)	0.3 (± 11.19)		
AST, Week 32, n=275, 294	-1.2 (± 16.08)	0.6 (± 13.40)		
AST, Week 36, n=273, 292	-1.2 (± 12.95)	0.1 (± 9.61)		
AST, Week 40, n=270, 293	-0.2 (± 17.27)	0.0 (± 10.64)		
AST, Week 44, n=275, 293	-1.1 (± 16.51)	0.1 (± 11.09)		
AST Week 48, n=265, 292	-1.0 (± 12.79)	0.7 (± 10.75)		
CK, Week 4, n=301, 303	-0.1 (± 548.15)	30.8 (± 435.12)		
CK, Week 8, n=229, 303	98.2 (± 1076.99)	-16.5 (± 344.96)		
CK, Week 12, n=295, 299	6.0 (± 585.45)	14.9 (± 288.85)		
CK, Week 16, n=284, 298	54.2 (± 882.23)	5.8 (± 411.52)		
CK, Week 20, n=277, 302	31.2 (± 653.11)	-16.7 (± 363.30)		
CK, Week 24, n=284, 299	-9.2 (± 538.95)	-0.7 (± 353.99)		
CK, Week 28, n=267, 296	-1.9 (± 213.98)	20.8 (± 538.83)		
CK, Week 32, n=275, 294	13.3 (± 699.60)	34.0 (± 597.29)		
CK, Week 36, n=273, 292	-18.2 (± 476.64)	-10.8 (± 358.72)		
CK, Week 40, n=270, 293	39.7 (± 704.18)	-0.3 (± 373.96)		
CK, Week 44, n=275, 293	47.4 (± 1185.55)	-10.9 (± 350.64)		
CK, Week 48, n=265, 292	-0.6 (± 528.71)	18.1 (± 463.49)		

Notes:

[61] - Safety Population

[62] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameter over time including Week 48: Albumin

End point title	Change from Baseline values for clinical chemistry parameter over time including Week 48: Albumin

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-albumin. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[63]	308[64]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Week 4, n=301, 303	-0.5 (± 2.60)	-0.5 (± 2.49)		
Week 8, n=229, 303	-0.3 (± 2.76)	-0.7 (± 2.70)		
Week 12, n=295, 299	-0.6 (± 2.72)	-0.4 (± 2.63)		
Week 16, n=284, 298	-0.6 (± 2.78)	-0.8 (± 2.70)		
Week 20, n=277, 302	-0.8 (± 2.78)	-0.8 (± 2.56)		
Week 24, n=284, 299	-0.7 (± 2.69)	-0.8 (± 2.59)		
Week 28, n=267, 296	-0.7 (± 2.60)	-1.0 (± 2.47)		
Week 32, n=275, 294	-0.6 (± 2.78)	-1.0 (± 2.56)		
Week 36, n=273, 292	-0.9 (± 2.71)	-0.9 (± 2.65)		
Week 40, n=270, 293	-0.5 (± 2.53)	-1.0 (± 2.61)		
Week 44, n=275, 293	-0.4 (± 2.58)	-0.8 (± 2.47)		
Week 48, n=265, 292	-0.4 (± 2.64)	-0.4 (± 2.55)		

Notes:

[63] - Safety Population

[64] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters over time including Week 48: Bilirubin, direct bilirubin and creatinine

End point title	Change from Baseline values for clinical chemistry parameters over time including Week 48: Bilirubin, direct bilirubin and creatinine

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including bilirubin, creatinine and direct bilirubin. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[65]	308[66]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin, Week 4, n=301, 303	-0.8 (± 9.87)	-0.3 (± 4.17)		

Bilirubin, Week 8, n=229, 303	-0.1 (± 6.92)	0.1 (± 7.66)		
Bilirubin, Week 12, n=295, 299	-0.6 (± 10.23)	0.1 (± 4.56)		
Bilirubin, Week 16, n=284, 298	0.2 (± 14.00)	-0.2 (± 4.12)		
Bilirubin, Week 20, n=277, 302	-0.2 (± 10.04)	0.0 (± 6.10)		
Bilirubin, Week 24, n=284, 298	-0.6 (± 9.90)	0.2 (± 5.90)		
Bilirubin, Week 28, n=267, 296	0.0 (± 10.46)	-0.1 (± 4.76)		
Bilirubin, Week 32, n=275, 294	-0.1 (± 10.36)	0.0 (± 4.94)		
Bilirubin, Week 36, n=273, 292	-0.6 (± 10.39)	0.1 (± 4.55)		
Bilirubin, Week 40, n=270, 293	-0.3 (± 10.61)	0.2 (± 6.28)		
Bilirubin, Week 44, n=275, 293	-0.4 (± 10.11)	0.4 (± 5.24)		
Bilirubin, Week 48, n=265, 292	-0.3 (± 10.57)	0.2 (± 3.91)		
Direct bilirubin, Week 4, n=301, 303	-0.1 (± 1.48)	0.1 (± 1.20)		
Direct bilirubin, Week 8, n=229, 303	-0.1 (± 1.42)	0.2 (± 3.96)		
Direct bilirubin, Week 12, n=295, 299	-0.2 (± 1.61)	0.1 (± 1.21)		
Direct bilirubin, Week 16, n=284, 298	0.1 (± 5.02)	-0.1 (± 1.12)		
Direct bilirubin, Week 20, n=277, 302	-0.3 (± 1.52)	-0.2 (± 1.29)		
Direct bilirubin, Week 24, n=284, 298	-0.2 (± 1.55)	-0.1 (± 1.24)		
Direct bilirubin, Week 28, n=267, 296	-0.3 (± 1.55)	-0.2 (± 1.29)		
Direct bilirubin, Week 32, n=275, 294	-0.3 (± 1.61)	-0.2 (± 1.24)		
Direct bilirubin, Week 36, n=273, 292	-0.3 (± 1.70)	-0.1 (± 1.20)		
Direct bilirubin, Week 40, n=270, 293	-0.3 (± 1.68)	-0.2 (± 1.18)		
Direct bilirubin, Week 44, n=275, 293	-0.2 (± 1.55)	-0.1 (± 1.19)		
Direct bilirubin, Week 48, n=265, 292	-0.2 (± 1.54)	0.0 (± 1.23)		
Creatinine, Week 4, n=301, 301	1.15 (± 8.205)	1.80 (± 8.022)		
Creatinine, Week 8, n=229, 303	-0.66 (± 9.042)	1.23 (± 7.560)		
Creatinine, Week 12, n=295, 299	-0.38 (± 9.380)	1.71 (± 7.638)		
Creatinine, Week 16, n=284, 298	-0.60 (± 9.225)	1.62 (± 8.169)		
Creatinine, Week 20, n=277, 302	0.53 (± 9.390)	1.80 (± 8.454)		
Creatinine, Week 24, n=284, 298	0.90 (± 12.494)	1.36 (± 8.038)		
Creatinine, Week 28, n=267, 296	1.14 (± 10.998)	1.59 (± 8.303)		
Creatinine, Week 32, n=275, 294	0.33 (± 10.102)	1.95 (± 8.331)		
Creatinine, Week 36, n=273, 292	0.34 (± 10.585)	1.62 (± 7.891)		
Creatinine, Week 40, n=270, 293	0.88 (± 9.986)	1.64 (± 8.318)		
Creatinine, Week 44, n=275, 293	1.03 (± 11.253)	1.40 (± 8.008)		
Creatinine, Week 48, n=265, 292	1.59 (± 11.253)	0.82 (± 7.846)		

Notes:

[65] - Safety Population

[66] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters over time including Week 48

End point title	Change from Baseline values for clinical chemistry parameters

	over time including Week 48

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters which includes total CO2, chloride, glucose, phosphate, potassium, sodium and urea. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[67]	308[68]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
CO2, Week 4, n=301, 303	1.0 (± 2.53)	0.7 (± 2.21)		
CO2, Week 8, n=229, 303	0.4 (± 2.31)	0.6 (± 2.52)		
CO2, Week 12, n=295, 299	0.5 (± 2.42)	0.3 (± 2.39)		
CO2, Week 16, n=284, 298	0.3 (± 2.42)	0.5 (± 2.41)		
CO2, Week 20, n=277, 302	0.2 (± 2.26)	0.3 (± 2.31)		
CO2, Week 24, n=284, 298	0.2 (± 2.46)	0.2 (± 2.44)		
CO2, Week 28, n=267, 296	0.1 (± 2.47)	0.1 (± 2.39)		
CO2, Week 32, n=275, 294	0.0 (± 2.37)	0.2 (± 2.31)		
CO2, Week 36, n=273, 292	0.2 (± 2.37)	0.3 (± 2.39)		
CO2, Week 40, n=270, 293	0.5 (± 2.49)	0.4 (± 2.29)		
CO2, Week 44, n=275, 293	0.5 (± 2.34)	0.5 (± 2.19)		
CO2, Week 48, n=265, 292	0.1 (± 2.41)	0.2 (± 2.31)		
Chloride, Week 4, n=301, 303	0.4 (± 2.05)	0.5 (± 2.13)		
Chloride, Week 8, n=229, 303	0.3 (± 2.12)	0.5 (± 2.19)		
Chloride, Week 12, n=295, 299	0.4 (± 2.30)	0.5 (± 2.25)		
Chloride, Week 16, n=284, 298	0.6 (± 2.41)	0.8 (± 2.25)		
Chloride, Week 20, n=277, 302	0.8 (± 2.32)	0.8 (± 2.38)		
Chloride, Week 24, n=284, 299	0.6 (± 2.48)	0.9 (± 2.26)		
Chloride, Week 28, n=267, 296	0.9 (± 2.21)	1.0 (± 2.55)		
Chloride, Week 32, n=275, 294	0.8 (± 2.41)	0.9 (± 2.33)		
Chloride, Week 36, n=273, 292	0.9 (± 2.18)	0.9 (± 2.48)		
Chloride, Week 40, n=270, 293	0.8 (± 2.24)	0.8 (± 2.76)		
Chloride, Week 44, n=275, 293	0.7 (± 2.20)	0.8 (± 2.28)		
Chloride, Week 48, n=265, 292	0.5 (± 2.36)	0.3 (± 2.38)		
Glucose, Week 4, n=218, 226	0.17 (± 0.721)	0.21 (± 0.900)		
Glucose, Week 8, n=151, 213	0.22 (± 0.841)	0.22 (± 0.832)		
Glucose, Week 12, n=204, 216	0.19 (± 0.855)	0.19 (± 0.974)		
Glucose, Week 16, n=207, 211	0.23 (± 1.050)	0.27 (± 1.084)		
Glucose, Week 20, n=192, 216	0.19 (± 0.712)	0.19 (± 0.961)		
Glucose, Week 24, n=212, 224	0.23 (± 0.710)	0.16 (± 0.881)		
Glucose, Week 28, n=188, 225	0.17 (± 0.793)	0.28 (± 0.903)		
Glucose, Week 32, n=192, 213	0.35 (± 0.956)	0.27 (± 0.939)		
Glucose, Week 36, n=190, 215	0.18 (± 0.803)	0.26 (± 1.070)		

Glucose, Week 40, n=193, 213	0.27 (± 0.833)	0.25 (± 0.891)		
Glucose, Week 44, n=193, 213	0.23 (± 0.895)	0.27 (± 0.898)		
Glucose, Week 48, n=238, 274	0.04 (± 0.693)	0.02 (± 0.924)		
Phosphate, Week 4, n=301, 303	0.066 (± 0.1666)	0.015 (± 0.1595)		
Phosphate, Week 8, n=229, 303	0.062 (± 0.1862)	-0.006 (± 0.1609)		
Phosphate, Week 12, n=295, 299	0.041 (± 0.1978)	0.013 (± 0.1742)		
Phosphate, Week 16, n=284, 298	0.041 (± 0.2012)	0.003 (± 0.1640)		
Phosphate, Week 20, n=277, 302	0.035 (± 0.1871)	0.010 (± 0.1839)		
Phosphate, Week 24, n=284, 299	0.042 (± 0.1963)	0.006 (± 0.1845)		
Phosphate, Week 28, n=267, 296	0.037 (± 0.1822)	0.004 (± 0.1823)		
Phosphate, Week 32, n=275, 294	0.021 (± 0.1980)	0.005 (± 0.1886)		
Phosphate, Week 36, n=273, 292	0.011 (± 0.1846)	-0.002 (± 0.1855)		
Phosphate, Week 40, n=270, 293	0.024 (± 0.2035)	-0.004 (± 0.1736)		
Phosphate, Week 44, n=275, 293	0.027 (± 0.1982)	0.004 (± 0.1811)		
Phosphate, Week 48, n=265, 292	0.034 (± 0.2007)	0.003 (± 0.1741)		
Potassium, Week 4, n=301, 303	0.05 (± 0.342)	0.11 (± 0.375)		
Potassium, Week 8, n=229, 303	0.01 (± 0.311)	0.06 (± 0.393)		
Potassium, Week 12, n=295, 299	0.04 (± 0.341)	0.08 (± 0.356)		
Potassium, Week 16, n=284, 298	0.01 (± 0.341)	0.06 (± 0.340)		
Potassium, Week 20, n=277, 302	0.04 (± 0.345)	0.05 (± 0.359)		
Potassium, Week 24, n=284, 298	0.03 (± 0.325)	0.07 (± 0.337)		
Potassium, Week 28, n=267, 296	0.04 (± 0.380)	0.07 (± 0.389)		
Potassium, Week 32, n=275, 294	0.02 (± 0.390)	0.05 (± 0.347)		
Potassium, Week 36, n=273, 292	0.03 (± 0.356)	0.07 (± 0.359)		
Potassium, Week 40, n=270, 293	0.04 (± 0.344)	0.07 (± 0.350)		
Potassium, Week 44, n=275, 293	0.06 (± 0.344)	0.07 (± 0.372)		
Potassium, Week 48, n=265, 292	-0.02 (± 0.299)	0.00 (± 0.332)		
Sodium, Week 4, n=301, 303	0.3 (± 1.84)	0.1 (± 1.99)		
Sodium, Week 8, n=229, 303	0.2 (± 1.99)	-0.1 (± 1.92)		
Sodium, Week 12, n=295, 299	0.2 (± 2.07)	0.2 (± 1.91)		
Sodium, Week 16, n=284, 298	0.1 (± 2.18)	0.1 (± 2.06)		
Sodium, Week 20, n=277, 302	0.3 (± 2.10)	0.3 (± 1.95)		
Sodium, Week 24, n=284, 299	0.3 (± 2.07)	0.2 (± 1.95)		
Sodium, Week 28, n=267, 296	0.5 (± 2.11)	0.2 (± 2.24)		
Sodium, Week 32, n=275, 294	0.3 (± 2.05)	0.4 (± 1.89)		
Sodium, Week 36, n=273, 292	0.5 (± 2.01)	0.5 (± 2.19)		
Sodium, Week 40, n=270, 293	0.4 (± 2.02)	0.5 (± 2.07)		
Sodium, Week 44, n=275, 293	0.5 (± 2.03)	0.5 (± 2.05)		
Sodium, Week 48, n=265, 292	0.4 (± 2.20)	0.3 (± 1.95)		
Urea, Week 4, n=301, 303	0.01 (± 1.369)	0.08 (± 1.334)		
Urea, Week 8, n=229, 303	0.07 (± 1.453)	0.00 (± 1.363)		
Urea, Week 12, n=295, 299	0.15 (± 1.409)	0.09 (± 1.381)		
Urea, Week 16, n=284, 298	0.08 (± 1.387)	0.19 (± 1.496)		

Urea, Week 20, n=277, 302	0.15 (± 1.399)	0.11 (± 1.461)		
Urea, Week 24, n=284, 299	0.25 (± 1.420)	0.15 (± 1.311)		
Urea, Week 28, n=267, 296	0.15 (± 1.524)	0.00 (± 1.439)		
Urea, Week 32, n=275, 294	0.20 (± 1.511)	0.06 (± 1.415)		
Urea, Week 36, n=273, 292	0.06 (± 1.420)	-0.02 (± 1.386)		
Urea, Week 40, n=270, 293	0.19 (± 1.400)	0.09 (± 1.452)		
Urea, Week 44, n=275, 293	0.13 (± 1.426)	0.02 (± 1.467)		
Urea, Week 48, n=265, 292	0.24 (± 1.465)	-0.01 (± 1.312)		

Notes:

[67] - Safety Population

[68] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for fasting lipid panel over time including Week 48

End point title	Change from Baseline values for fasting lipid panel over time including Week 48

End point description:

Blood samples were collected for the analysis of fasting lipid parameters- total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at specified data points were analyzed(represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[69]	308[70]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Total cholesterol, Week 48, n=231, 242	0.08 (± 0.688)	-0.04 (± 0.665)		
HDL cholesterol, Week 48, n=231, 242	0.040 (± 0.2702)	0.002 (± 0.2682)		
LDL cholesterol, Week 48, n=224, 238	0.098 (± 0.6105)	-0.017 (± 0.5314)		
Triglycerides, Week 48, n=231, 242	-0.159 (± 0.8670)	-0.033 (± 0.7844)		

Notes:

[69] - Safety Population

[70] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameter over time including Week 48: Lipase

End point title	Change from Baseline values for clinical chemistry parameter over time including Week 48: Lipase

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-lipase. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[71]	308[72]		
Units: Units per liter				
arithmetic mean (standard deviation)				
Week 4, n=301, 303	5.2 (± 41.42)	1.5 (± 23.88)		
Week 8, n=227, 303	1.2 (± 19.31)	1.0 (± 17.96)		
Week 12, n=294, 297	2.7 (± 25.12)	-0.8 (± 18.59)		
Week 16, n=285, 299	2.6 (± 24.79)	3.5 (± 31.03)		
Week 20, n=278, 302	0.9 (± 15.65)	0.8 (± 28.95)		
Week 24, n=283, 299	2.1 (± 20.79)	3.0 (± 23.85)		
Week 28, n=267, 297	2.2 (± 24.93)	2.3 (± 18.96)		
Week 32, n=274, 294	5.2 (± 57.44)	3.1 (± 21.31)		
Week 36, n=273, 292	5.1 (± 49.92)	0.7 (± 17.39)		
Week 40, n=269, 293	5.1 (± 33.58)	0.5 (± 17.60)		
Week 44, n=274, 293	2.0 (± 22.57)	2.3 (± 21.13)		
Week 48, n=264, 290	3.0 (± 28.26)	1.5 (± 19.00)		

Notes:

[71] - Safety Population

[72] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameter over time including Week 48: Creatinine clearance

End point title	Change from Baseline values for clinical chemistry parameter over time including Week 48: Creatinine clearance

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-creatinine clearance. GFR was estimated by the central laboratory using the CKD-EPI. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[73]	308[74]		
Units: Milliliters per minute per 1.73meter^2				
arithmetic mean (standard deviation)				
Week 4, n=301, 301	-1.8 (± 9.51)	-2.3 (± 9.18)		
Week 8, n=227, 303	0.4 (± 9.88)	-1.5 (± 8.06)		
Week 12, n=295, 297	0.3 (± 10.28)	-1.9 (± 8.02)		
Week 16, n=284, 297	0.4 (± 10.63)	-1.9 (± 8.69)		
Week 20, n=277, 302	-1.0 (± 10.37)	-2.4 (± 8.55)		
Week 24, n=283, 298	-1.0 (± 10.52)	-2.3 (± 8.76)		
Week 28, n=267, 296	-1.8 (± 11.47)	-2.4 (± 8.93)		
Week 32, n=274, 294	-1.2 (± 11.11)	-3.0 (± 8.94)		
Week 36, n=273, 292	-1.2 (± 11.26)	-2.6 (± 8.52)		
Week 40, n=268, 293	-1.7 (± 10.70)	-2.7 (± 9.10)		
Week 44, n=274, 293	-2.1 (± 10.45)	-2.3 (± 8.74)		
Week 48, n=264, 291	-2.5 (± 11.80)	-1.9 (± 8.50)		

Notes:

[73] - Safety Population

[74] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine albumin/creatinine ratio and urine protein/creatinine ratio over time including Week 48

End point title	Change from Baseline values in urine albumin/creatinine ratio and urine protein/creatinine ratio over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine albumin/creatinine ratio and urine protein/creatinine ratio.Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[75]	308[76]		
Units: Grams per mole				
arithmetic mean (standard deviation)				

Urine albumin/creatinine ratio, Week 4,n=210, 221	0.32 (± 3.948)	0.06 (± 6.383)		
Urine albumin/creatinine ratio, Week 24,n=198, 208	-0.08 (± 3.360)	-0.11 (± 8.552)		
Urine albumin/creatinine ratio, Week 48,n=191, 197	0.15 (± 6.049)	-0.14 (± 5.286)		
Urine protein/creatinine, Week 4, n=234, 236	-0.66 (± 11.803)	1.85 (± 31.997)		
Urine protein/creatinine, Week 24, n=208, 232	-2.49 (± 8.028)	1.67 (± 20.505)		
Urine protein/creatinine, Week 48, n=206, 225	-1.72 (± 9.551)	6.70 (± 112.353)		

Notes:

[75] - Safety Population

[76] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine creatinine over time including Week 48

End point title	Change from Baseline values in urine creatinine over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine creatinine. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[77]	308[78]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Week 4, n=304, 302	-543.9 (± 8693.94)	-305.5 (± 8787.62)		
Week 24, n=282, 297	-341.8 (± 9286.26)	-270.4 (± 8437.76)		
Week 48, n=282, 291	-342.9 (± 8965.01)	-521.6 (± 7873.28)		

Notes:

[77] - Safety Population

[78] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine phosphate over time including

Week 48

End point title	Change from Baseline values in urine phosphate over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine phosphate. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[79]	308[80]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Week 4, n=302, 300	-0.460 (± 15.2707)	1.483 (± 15.0378)		
Week 24, n=281, 294	0.286 (± 16.1887)	0.640 (± 14.4201)		
Week 48, n=280, 291	-0.369 (± 14.2441)	1.254 (± 15.6532)		

Notes:

[79] - Safety Population

[80] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine retinol binding protein over time including Week 48

End point title	Change from Baseline values in urine retinol binding protein over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine retinol binding protein. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	275[81]	284[82]		
Units: Nanomoles per liter				
arithmetic mean (standard deviation)	-1.8913 (± 14.10125)	1.4289 (± 15.70559)		

Notes:

[81] - Safety Population

[82] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine specific gravity over time including Week 48

End point title	Change from Baseline values in urine specific gravity over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine specific gravity. Urine specific gravity is a measure of the concentration of solutes in the urine and provides information on the kidney's ability to concentrate urine. The dipstick test gives results in a semi-quantitative manner. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. The urine specific gravity was measured as the ratio of urine density compared with water density. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[83]	308[84]		
Units: Ratio of urine density to water density				
arithmetic mean (standard deviation)				
Week 4, n=298, 295	-0.0009 (± 0.00800)	-0.0000 (± 0.00785)		
Week 24, n=274, 291	-0.0008 (± 0.00784)	-0.0000 (± 0.00770)		
Week 48, n=274, 283	-0.0009 (± 0.00772)	-0.0002 (± 0.00768)		

Notes:

[83] - Safety Population

[84] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine pH over time including Week 48

End point title	Change from Baseline values in urine pH over time including

	Week 48

End point description:

Urine samples were collected for analysis of urine pH. pH is calculated on a scale of 0 to 14, values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH of less than 7 is acidic and a pH of greater than 7 is basic. Normal urine has a slightly acidic pH (5.0-6.0). The dipstick test gives results in a semi-quantitative manner. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[85]	308[86]		
Units: pH				
arithmetic mean (standard deviation)				
Week 4, n=298, 295	0.08 (± 0.886)	-0.13 (± 0.935)		
Week 24, n=274, 291	0.18 (± 1.021)	0.01 (± 0.870)		
Week 48, n=274, 283	0.09 (± 1.036)	-0.02 (± 0.951)		

Notes:

[85] - Safety population

[86] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who discontinued or withdrawn due to AEs over time including Week 48

End point title	Number of participants who discontinued or withdrawn due to AEs over time including Week 48

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[87]	308[88]		
Units: Participants	13	5		

Notes:

[87] - Safety Population

[88] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage change from Baseline in fasting lipids overtime including Week 48

End point title	Percentage change from Baseline in fasting lipids overtime including Week 48

End point description:

Blood samples were collected at Baseline and at Week 48 to assess fasting lipids which included total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Percentage change from Baseline is calculated as: value at Week 48 minus Baseline value divided by Baseline value multiplied by 100. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[89]	308[90]		
Units: Percent change				
arithmetic mean (standard deviation)				
Cholesterol, Week 48, Overall, n=231, 242	3.25 (± 15.563)	0.13 (± 13.379)		
HDL cholesterol, Week 48, Overall, n=231, 242	5.059 (± 20.5368)	2.132 (± 18.0473)		
LDL cholesterol, Week 48, Overall, n=224, 238	6.762 (± 31.7209)	1.029 (± 19.4719)		
Triglycerides, Week 48, Overall, n=231, 242	0.708 (± 43.5160)	8.203 (± 51.7632)		

Notes:

[89] - Safety Population

[90] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with phenotypic resistance through Week 48

End point title	Number of participants with phenotypic resistance through Week 48

End point description:

The CVF population comprised of ITT-E population meeting CVF criteria.Phenotypic Resistancedatafordrugs:CAB,dolutegravir(DTG),elvitegravir(EVG),raltegravir(RAL),delavirdine(DLV),

efavirenz(EFV),etravirine(ETR),nevirapine(NVP),RPV,lamivudine(3TC),abacavir(ABC),emtricitabine(FTC), tenofovir(TDF),zidovudine(ZDV),stavudine(d4T),didanosine(ddI),atazanavir(ATV),darunavir(DRV),fosam prenavir(FPV),indinavir(IDV),lopinavir(LPV),nelfinavir(NFV),rito-navir(RTV),saquinavir(SQV) and tipranavir(TPV) in participants meeting CVF criteria is presented.Phenotypic resistance,partiallysensitive, and Sensitive were based on fold change(FC) value fromMonogram:resistance(FC>clinical higher cutoff/biologic cutoff),partially sensitive(FC<=clinical higher cutoff and >clinical lower cutoff),sensitive(FC<=clinical lower cutoff/biologic cutoff).Only those participants with data available at specified data points were analyzed(represented by n=X in category titles)

End point type	Secondary

End point timeframe:

At the time of CVF

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[91]	4[92]		
Units: Participants				
INI, CAB, resistant, n=3, 4	1	0		
INI, CAB, sensitive, n=3, 4	2	4		
INI, DTG, resistant, n=3, 4	0	0		
INI, DTG, partially sensitive, n=3, 4	0	0		
INI, DTG, sensitive, n=3, 4	3	4		
INI, EVG, resistant, n=3, 4	1	0		
INI, EVG, sensitive, n=3, 4	2	4		
INI, RAL, resistant, n=3, 4	1	0		
INI, RAL, sensitive, n=3, 4	2	4		
NNRTI, DLV, resistant, n=3, 3	2	0		
NNRTI, DLV, sensitive, n=3, 3	1	3		
NNRTI, EFV, resistant, n=3, 3	2	0		
NNRTI, EFV, sensitive, n=3, 3	1	3		
NNRTI, ETR, resistant, n=3, 3	0	0		
NNRTI, ETR, partially sensitive, n=3, 3	2	0		
NNRTI, ETR, sensitive, n=3, 3	1	3		
NNRTI, NVP, resistant, n=3, 3	2	0		
NNRTI, NVP, sensitive, n=3, 3	1	3		
NNRTI, RPV, resistant, n=3, 3	3	0		
NNRTI, RPV, sensitive, n=3, 3	0	3		
NRTI, 3TC, resistant, n=3, 3	0	1		
NRTI, 3TC, sensitive, n=3, 3	3	2		
NRTI, ABC, resistant, n=3, 3	0	0		
NRTI, ABC, partially sensitive, n=3, 3	0	0		
NRTI, ABC, sensitive, n=3, 3	3	3		
NRTI, FTC, resistant, n=3, 3	0	1		
NRTI, FTC, sensitive, n=3, 3	3	2		
NRTI, TDF, resistant, n=3, 3	0	0		
NRTI, TDF, partially sensitive, n=3, 3	0	0		
NRTI, TDF, sensitive, n=3, 3	3	3		
NRTI, ZDV, resistant, n=3, 3	1	0		
NRTI, ZDV, sensitive, n=3, 3	2	3		
NRTI, d4T, resistant, n=3, 3	0	0		
NRTI, d4T, sensitive, n=3, 3	3	3		

NRTI, ddI, resistant, n=3, 3	0	0		
NRTI, ddI, partially sensitive, n=3, 3	0	0		
NRTI, ddI, sensitive, n=3, 3	3	3		
PI, ATV, resistant, n=3, 3	0	0		
PI, ATV, sensitive, n=3, 3	3	3		
PI, DRV, resistant, n=3, 3	0	0		
PI, DRV, partially sensitive, n=3, 3	0	0		
PI, DRV, sensitive, n=3, 3	3	3		
PI, FPV, resistant, n=3, 3	0	0		
PI, FPV, partially sensitive, n=3, 3	0	0		
PI, FPV, sensitive, n=3, 3	3	3		
PI, IDV, resistant, n=3, 3	0	0		
PI, IDV, sensitive, n=3, 3	3	3		
PI, LPV, resistant, n=3, 3	0	0		
PI, LPV, partially sensitive, n=3, 3	0	0		
PI, LPV, sensitive, n=3, 3	3	3		
PI, NFV, resistant, n=3, 3	0	0		
PI, NFV, sensitive, n=3, 3	3	3		
PI, RTV, resistant, n=3, 3	0	0		
PI, RTV, sensitive, n=3, 3	3	3		
PI, SQV, resistant, n=3, 3	0	0		
PI, SQV, partially sensitive, n=3, 3	0	0		
PI, SQV, sensitive, n=3, 3	3	3		
PI, TPV, resistant, n=3, 3	0	0		
PI, TPV, partially sensitive, n=3, 3	0	0		
PI, TPV, sensitive, n=3, 3	3	3		

Notes:

[91] - CVF Population

[92] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with genotypic resistance through Week 48

End point title	Number of participants with genotypic resistance through Week 48

End point description:

Plasma samples were collected and analyzed from participants who met confirmed virologic withdrawal criteria. Genotypic Resistance data for the following drugs: DTG, EVG, RAL, DLV, EFV, ETR, NVP, RPV, 3TC, ABC, FTC, TDF, ZDV, d4T, ddI, ATV, DRV, FPV, IDV, LPV, NFV, RTV, SQV and TPV in participants meeting CVF criteria has been presented. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

At the time of CVF

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[93]	4[94]		
Units: Participants				
INI, DTG, resistant	0	0		
INI, DTG, resistance possible	0	0		
INI, DTG, sensitive	3	4		
INI, EVG, resistant	1	0		
INI, EVG, resistance possible	0	0		
INI, EVG, sensitive	2	4		
INI, RAL, resistant	1	0		
INI, RAL, resistance possible	0	0		
INI, RAL, sensitive	2	4		
NNRTI, DLV, resistant	0	0		
NNRTI, DLV, resistance possible	0	0		
NNRTI, DLV, sensitive	3	4		
NNRTI, EFV, resistant	1	1		
NNRTI, EFV, resistance possible	0	0		
NNRTI, EFV, sensitive	2	3		
NNRTI, ETR, resistant	0	0		
NNRTI, ETR, resistance possible	2	0		
NNRTI, ETR, sensitive	1	4		
NNRTI, NVP, resistant	1	1		
NNRTI, NVP, resistance possible	0	0		
NNRTI, NVP, sensitive	2	3		
NNRTI, RPV, resistant	3	1		
NNRTI, RPV, resistance possible	0	0		
NNRTI, RPV, sensitive	0	3		
NRTI, 3TC, resistant	0	2		
NNRTI, 3TC, resistance possible	0	0		
NRTI, 3TC, sensitive	3	2		
NRTI, ABC, resistant	0	0		
NRTI, ABC, resistance possible	0	0		
NRTI, ABC, sensitive	3	4		
NRTI, FTC, resistant	0	2		
NRTI, FTC, resistance possible	0	0		
NRTI, FTC, sensitive	3	2		
NRTI, TDF, resistant	0	0		
NRTI, TDF, resistance possible	0	0		
NRTI, TDF, sensitive	3	4		
NRTI, ZDV, resistant	0	0		
NRTI, ZDV, resistance possible	0	0		
NRTI, ZDV, sensitive	3	4		
NRTI, d4T, resistant	0	0		
NRTI, d4T, resistance possible	0	0		
NRTI, d4T, sensitive	3	4		
NRTI, ddI, resistant	0	0		
NRTI, ddI, resistance possible	0	2		
NRTI, ddI, sensitive	3	2		
PI, ATV, resistant	1	0		
PI, ATV, resistance possible	0	0		

PI, ATV, sensitive	2	4		
PI, ATV/r, resistant	0	0		
PI, ATV/r, resistance possible	1	0		
PI, ATV/r, sensitive	2	4		
PI, DRV/r, resistant	0	0		
PI, DRV/r, resistance possible	0	0		
PI, DRV/r, sensitive	3	4		
PI, FPV/r, resistant	0	0		
PI, FPV/r, resistance possible	0	0		
PI, FPV/r, sensitive	3	4		
PI, IDV/r, resistant	0	0		
PI, IDV/r, resistance possible	0	0		
PI, IDV/r, sensitive	3	4		
PI, LPV/r, resistant	0	0		
PI, LPV/r, resistance possible	0	0		
PI, LPV/r, sensitive	3	4		
PI, NFV, resistant	1	0		
PI, NFV, resistance possible	0	0		
PI, NFV, sensitive	2	4		
PI, RTV, resistant	0	0		
PI, RTV, resistance possible	0	0		
PI, RTV, sensitive	3	4		
PI, SQV/r, resistant	0	0		
PI, SQV/r, resistance possible	0	0		
PI, SQV/r, sensitive	3	4		
PI, TPV/r, resistant	0	0		
PI, TPV/r, resistance possible	0	0		
PI, TPV/r, sensitive	3	4		

Notes:

[93] - CVF Population

[94] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with AEs by using Baseline third agent treatment class overtime including Week 48

End point title	Number of participants with AEs by using Baseline third agent treatment class overtime including Week 48

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment.Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[95]	308[96]		
Units: Participants				
Any AE, INI, n=102, 99	99	68		
Any AE, NNRTI, n=155, 155	148	116		
Any AE, PI, n=51, 54	47	36		

Notes:

[95] - Safety Population

[96] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: ALT, ALP, AST and CK

End point title	Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: ALT, ALP, AST and CK

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[97]	308[98]		
Units: International units per liter				
arithmetic mean (standard deviation)				
PI, ALT, Baseline, n=51, 54	19.3 (± 11.23)	18.7 (± 9.13)		
PI, ALT, Week 4, n=51, 53	28.7 (± 20.12)	19.8 (± 12.29)		
PI, ALT, Week 8, n=34, 53	25.8 (± 19.28)	19.6 (± 10.43)		
PI, ALT, Week 12, n=50, 52	24.7 (± 17.09)	20.1 (± 14.19)		
PI, ALT, Week 16, n=48, 53	26.3 (± 19.89)	20.0 (± 12.04)		
PI, ALT, Week 20, n=46, 53	24.9 (± 18.46)	19.0 (± 9.52)		
PI, ALT, Week 24, n=47, 53	24.1 (± 13.75)	19.1 (± 10.02)		
PI, ALT, Week 28, n=42, 53	22.0 (± 12.42)	19.4 (± 10.45)		
PI, ALT, Week 32, n=45, 51	22.7 (± 15.18)	18.8 (± 8.18)		
PI, ALT, Week 36, n=44, 50	22.3 (± 15.09)	20.7 (± 13.18)		
PI, ALT, Week 40, n=42, 51	24.9 (± 19.63)	19.5 (± 13.46)		
PI, ALT, Week 44, n=47, 51	23.2 (± 17.05)	19.3 (± 14.23)		
PI, ALT, Week 48, n=43, 50	22.5 (± 13.28)	19.0 (± 8.52)		
INI, ALT, Baseline, n=102, 99	24.8 (± 15.23)	21.2 (± 10.93)		
INI, ALT, Week 4, n=99, 97	26.5 (± 18.35)	21.7 (± 10.09)		
INI, ALT, Week 8, n=73, 98	28.4 (± 22.77)	26.8 (± 49.37)		

INI, ALT, Week 12, n=99, 95	23.8 (± 14.21)	22.9 (± 16.05)		
INI, ALT, Week 16, n=93, 96	23.2 (± 13.62)	21.2 (± 11.24)		
INI, ALT, Week 20, n=93, 97	23.0 (± 15.29)	20.7 (± 9.83)		
INI, ALT, Week 24, n=94, 95	25.7 (± 20.09)	21.0 (± 13.40)		
INI, ALT, Week 28, n=89, 93	21.5 (± 13.06)	20.9 (± 14.10)		
INI, ALT, Week 32, n=93, 95	22.5 (± 10.95)	21.1 (± 12.32)		
INI, ALT, Week 36, n=94, 95	26.5 (± 38.41)	20.5 (± 9.38)		
INI, ALT, Week 40, n=90, 95	30.2 (± 61.80)	20.6 (± 9.20)		
INI, ALT, Week 44, n=91, 94	23.2 (± 15.03)	20.7 (± 10.01)		
INI, ALT, Week 48, n=91, 95	24.4 (± 17.58)	20.3 (± 9.79)		
NNRTI, ALT, Baseline, n=155, 155	24.6 (± 12.67)	24.4 (± 14.74)		
NNRTI, ALT, Week 4, n=151, 153	21.6 (± 10.72)	23.7 (± 11.16)		
NNRTI, ALT, Week 8, n=122, 152	20.8 (± 10.13)	23.7 (± 12.94)		
NNRTI, ALT, Week 12, n=146, 152	33.9 (± 161.81)	23.6 (± 11.27)		
NNRTI, ALT, Week 16, n=143, 149	23.2 (± 27.18)	22.8 (± 11.06)		
NNRTI, ALT, Week 20, n=138, 152	22.6 (± 27.36)	22.3 (± 11.15)		
NNRTI, ALT, Week 24, n=143, 151	27.4 (± 85.70)	22.9 (± 12.88)		
NNRTI, ALT, Week 28, n=136, 150	20.6 (± 11.45)	23.8 (± 16.00)		
NNRTI, ALT, Week 32, n=137, 148	21.1 (± 12.69)	23.4 (± 12.86)		
NNRTI, ALT, Week 36, n=135, 147	21.2 (± 12.38)	24.1 (± 13.19)		
NNRTI, ALT, Week 40, n=138, 147	20.8 (± 10.63)	23.9 (± 14.24)		
NNRTI, ALT, Week 44, n=137, 148	20.0 (± 9.61)	23.9 (± 15.22)		
NNRTI, ALT, Week 48, n=131, 147	19.8 (± 9.62)	23.5 (± 12.32)		
PI, ALP, Baseline, n=51, 54	73.8 (± 24.90)	70.2 (± 19.56)		
PI, ALP, Week 4, n=51, 53	70.4 (± 20.03)	67.7 (± 19.24)		
PI, ALP, Week 8, n=34, 53	72.4 (± 34.86)	70.9 (± 23.18)		
PI, ALP, Week 12, n=50, 52	68.2 (± 17.49)	71.6 (± 23.60)		
PI, ALP, Week 16, n=48, 53	66.9 (± 15.70)	71.2 (± 21.50)		
PI, ALP, Week 20, n=46, 53	67.7 (± 16.36)	70.8 (± 20.96)		
PI, ALP, Week 24, n=47, 53	67.6 (± 16.14)	70.3 (± 19.23)		
PI, ALP, Week 28, n=42, 53	67.3 (± 17.71)	73.7 (± 21.89)		
PI, ALP, Week 32, n=45, 51	63.8 (± 16.09)	69.8 (± 21.44)		
PI, ALP, Week 36, n=44, 50	64.3 (± 16.50)	71.7 (± 23.57)		
PI, ALP, Week 40, n=42, 51	65.5 (± 13.63)	68.5 (± 19.55)		
PI, ALP, Week 44, n=47, 51	63.0 (± 15.76)	69.1 (± 20.67)		
PI, ALP, Week 48, n=43, 50	63.6 (± 14.22)	69.9 (± 18.94)		
INI, ALP, Baseline, n=102, 99	66.3 (± 17.31)	64.9 (± 19.05)		
INI, ALP, Week 4, n=99, 97	65.9 (± 17.25)	64.4 (± 18.77)		
INI, ALP, Week 8, n=73, 98	64.0 (± 16.21)	69.7 (± 38.92)		
INI, ALP, Week 12, n=99, 95	64.7 (± 16.33)	67.7 (± 27.73)		
INI, ALP, Week 16, n=93, 96	65.3 (± 17.01)	64.4 (± 20.89)		
INI, ALP, Week 20, n=93, 97	64.9 (± 16.80)	64.2 (± 19.58)		
INI, ALP, Week 24, n=94, 95	65.0 (± 17.08)	64.4 (± 19.46)		
INI, ALP, Week 28, n=89, 93	65.0 (± 15.81)	63.3 (± 18.76)		
INI, ALP, Week 32, n=93, 95	64.4 (± 16.12)	62.3 (± 17.96)		
INI, ALP, Week 36, n=94, 95	64.3 (± 18.15)	62.2 (± 18.12)		
INI, ALP, Week 40, n=90, 95	65.1 (± 17.07)	62.2 (± 18.22)		
INI, ALP, Week 44, n=91, 94	64.0 (± 16.71)	64.1 (± 19.31)		
INI, ALP, Week 48, n=91, 95	65.1 (± 15.98)	63.0 (± 18.76)		
NNRTI, ALP, Baseline, n=155, 155	84.4 (± 32.47)	88.1 (± 28.83)		
NNRTI, ALP, Week 4, n=151, 153	73.4 (± 26.16)	85.6 (± 27.39)		

NNRTI, ALP, Week 8, n=122, 152	70.9 (± 20.00)	87.4 (± 28.15)		
NNRTI, ALP, Week 12, n=146, 152	72.0 (± 30.68)	87.8 (± 28.30)		
NNRTI, ALP, Week 16, n=143, 149	69.9 (± 22.37)	87.7 (± 28.55)		
NNRTI, ALP, Week 20, n=138, 152	69.3 (± 20.51)	86.7 (± 26.18)		
NNRTI, ALP, Week 24, n=143, 151	70.2 (± 21.08)	88.3 (± 27.77)		
NNRTI, ALP, Week 28, n=136, 150	69.3 (± 20.91)	87.0 (± 28.40)		
NNRTI, ALP, Week 32, n=137, 148	69.1 (± 21.60)	86.5 (± 26.32)		
NNRTI, ALP, Week 36, n=135, 147	69.3 (± 23.22)	87.1 (± 26.24)		
NNRTI, ALP, Week 40, n=138, 147	67.1 (± 18.98)	87.8 (± 27.07)		
NNRTI, ALP, Week 44, n=137, 148	68.4 (± 19.94)	87.5 (± 26.53)		
NNRTI, ALP, Week 48, n=131, 147	68.5 (± 21.69)	88.6 (± 27.61)		
PI, AST, Baseline, n=51, 54	19.7 (± 6.97)	20.1 (± 5.66)		
PI, AST, Week 4, n=51, 53	23.5 (± 9.76)	22.5 (± 17.53)		
PI, AST, Week 8, n=34, 53	23.4 (± 11.04)	20.0 (± 5.24)		
PI, AST, Week 12, n=50, 52	22.5 (± 11.60)	21.8 (± 9.63)		
PI, AST, Week 16, n=48, 53	23.7 (± 15.77)	22.0 (± 10.39)		
PI, AST, Week 20, n=46, 53	24.1 (± 20.53)	20.6 (± 6.35)		
PI, AST, Week 24, n=47, 53	21.5 (± 7.02)	21.7 (± 11.65)		
PI, AST, Week 28, n=42, 53	22.9 (± 9.20)	22.0 (± 8.47)		
PI, AST, Week 32, n=45, 51	23.0 (± 13.51)	20.3 (± 5.57)		
PI, AST, Week 36, n=44, 50	21.5 (± 7.88)	21.8 (± 7.04)		
PI, AST, Week 40, n=42, 51	25.1 (± 23.51)	20.5 (± 7.55)		
PI, AST, Week 44, n=47, 51	21.6 (± 8.80)	21.4 (± 13.16)		
PI, AST, Week 48, n=43, 50	21.6 (± 7.59)	22.2 (± 8.85)		
INI, AST, Baseline, n=102, 99	24.5 (± 13.03)	22.2 (± 13.13)		
INI, AST, Week 4, n=99, 97	24.5 (± 13.22)	22.0 (± 10.41)		
INI, AST, Week 8, n=73, 98	26.8 (± 25.34)	23.6 (± 19.30)		
INI, AST, Week 12, n=99, 95	23.2 (± 10.47)	23.2 (± 13.10)		
INI, AST, Week 16, n=93, 96	22.5 (± 8.78)	22.5 (± 9.96)		
INI, AST, Week 20, n=93, 97	22.8 (± 10.11)	21.4 (± 6.12)		
INI, AST, Week 24, n=94, 95	24.4 (± 12.42)	22.0 (± 9.44)		
INI, AST, Week 28, n=89, 93	21.3 (± 7.14)	21.6 (± 8.49)		
INI, AST, Week 32, n=93, 95	22.2 (± 7.77)	21.6 (± 7.87)		
INI, AST, Week 36, n=94, 95	23.9 (± 15.06)	21.1 (± 5.43)		
INI, AST, Week 40, n=90, 95	25.4 (± 18.01)	21.8 (± 7.30)		
INI, AST, Week 44, n=91, 94	25.6 (± 23.29)	21.4 (± 6.51)		
INI, AST, Week 48, n=91, 95	24.9 (± 13.88)	22.4 (± 9.70)		
NNRTI, AST, Baseline, n=155, 155	24.8 (± 10.99)	23.6 (± 9.16)		
NNRTI, AST, Week 4, n=151, 153	22.2 (± 11.35)	23.2 (± 7.95)		
NNRTI, AST, Week 8, n=122, 152	23.0 (± 17.16)	22.8 (± 7.19)		
NNRTI, AST, Week 12, n=146, 152	29.4 (± 91.34)	23.6 (± 9.12)		
NNRTI, AST, Week 16, n=143, 149	25.3 (± 22.91)	22.6 (± 6.80)		
NNRTI, AST, Week 20, n=138, 152	23.8 (± 16.12)	22.9 (± 7.33)		
NNRTI, AST, Week 24, n=143, 150	25.1 (± 30.40)	23.1 (± 8.25)		
NNRTI, AST, Week 28, n=136, 150	22.6 (± 9.49)	24.0 (± 10.53)		
NNRTI, AST, Week 32, n=137, 148	23.2 (± 16.69)	25.1 (± 15.63)		
NNRTI, AST, Week 36, n=135, 147	22.8 (± 8.90)	23.9 (± 7.99)		
NNRTI, AST, Week 40, n=138, 147	22.3 (± 7.66)	23.7 (± 8.01)		
NNRTI, AST, Week 44, n=137, 148	21.7 (± 7.11)	23.8 (± 10.98)		
NNRTI, AST, Week 48, n=131, 147	22.0 (± 7.86)	24.2 (± 9.16)		
PI, CK, Baseline, n=51, 54	121.3 (± 173.52)	111.8 (± 66.03)		

PI, CK, Week 4, n=51, 53	130.0 (± 94.61)	244.2 (± 908.06)		
PI, CK, Week 8, n=34, 53	157.7 (± 174.37)	134.2 (± 179.01)		
PI, CK, Week 12, n=50, 52	124.2 (± 71.36)	168.8 (± 406.86)		
PI, CK, Week 16, n=48, 53	142.3 (± 197.96)	127.0 (± 82.59)		
PI, CK, Week 20, n=46, 53	227.9 (± 689.65)	117.5 (± 76.83)		
PI, CK, Week 24, n=47, 53	120.8 (± 72.63)	128.9 (± 85.38)		
PI, CK, Week 28, n=42, 53	185.9 (± 237.49)	124.2 (± 96.15)		
PI, CK, Week 32, n=45, 51	282.5 (± 959.49)	110.1 (± 58.84)		
PI, CK, Week 36, n=44, 50	115.5 (± 81.36)	130.9 (± 95.59)		
PI, CK, Week 40, n=42, 51	319.4 (± 1169.15)	109.9 (± 53.99)		
PI, CK, Week 44, n=47, 51	117.2 (± 74.25)	114.4 (± 62.44)		
PI, CK, Week 48, n=43, 50	123.5 (± 90.77)	183.1 (± 485.07)		
INI, CK, Baseline, n=102, 99	257.9 (± 565.99)	214.3 (± 627.94)		
INI, CK, Week 4, n=99, 97	225.9 (± 484.50)	193.6 (± 415.15)		
INI, CK, Week 8, n=73, 98	306.8 (± 791.76)	158.0 (± 164.72)		
INI, CK, Week 12, n=99, 95	242.5 (± 649.06)	195.3 (± 383.74)		
INI, CK, Week 16, n=93, 96	198.6 (± 335.16)	216.4 (± 422.21)		
INI, CK, Week 20, n=93, 97	200.9 (± 301.61)	158.8 (± 156.94)		
INI, CK, Week 24, n=94, 95	202.1 (± 276.49)	178.8 (± 356.60)		
INI, CK, Week 28, n=89, 93	151.1 (± 128.42)	192.6 (± 463.71)		
INI, CK, Week 32, n=93, 95	182.2 (± 202.28)	175.1 (± 256.84)		
INI, CK, Week 36, n=94, 95	190.7 (± 268.67)	153.8 (± 151.29)		
INI, CK, Week 40, n=90, 95	286.9 (± 705.76)	178.2 (± 200.25)		
INI, CK, Week 44, n=91, 94	457.7 (± 2054.68)	153.6 (± 139.48)		
INI, CK, Week 48, n=91, 95	278.9 (± 651.96)	188.7 (± 339.93)		
NNRTI, CK, Baseline, n=155, 155	180.9 (± 210.84)	143.8 (± 118.05)		
NNRTI, CK, Week 4, n=151, 153	192.5 (± 472.95)	170.1 (± 226.58)		
NNRTI, CK, Week 8, n=122, 152	290.4 (± 1322.89)	141.1 (± 106.01)		
NNRTI, CK, Week 12, n=146, 152	198.5 (± 430.65)	168.5 (± 236.30)		
NNRTI, CK, Week 16, n=143, 149	326.5 (± 1157.93)	150.4 (± 214.31)		
NNRTI, CK, Week 20, n=138, 152	247.2 (± 661.97)	144.9 (± 131.72)		

NNRTI, CK, Week 24, n=143, 151	210.9 (± 582.66)	161.5 (± 182.51)		
NNRTI, CK, Week 28, n=136, 150	175.0 (± 156.46)	197.3 (± 460.97)		
NNRTI, CK, Week 32, n=137, 148	218.0 (± 617.20)	238.8 (± 656.12)		
NNRTI, CK, Week 36, n=135, 147	206.4 (± 401.19)	155.5 (± 134.30)		
NNRTI, CK, Week 40, n=138, 147	175.6 (± 156.39)	166.9 (± 191.28)		
NNRTI, CK, Week 44, n=137, 148	148.6 (± 94.67)	159.7 (± 171.66)		
NNRTI, CK, Week 48, n=131, 147	167.8 (± 132.83)	171.3 (± 256.04)		

Notes:

[97] - Safety Population

[98] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Albumin

End point title	Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Albumin

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: albumin to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). . Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[99]	308[100]		
Units: Grams per Liter				
arithmetic mean (standard deviation)				
PI, Baseline, n=51, 54	43.9 (± 3.22)	44.2 (± 3.36)		
PI, Week 4, n=51, 53	44.1 (± 2.90)	43.9 (± 2.92)		
PI, Week 8, n=34, 53	44.6 (± 3.36)	44.1 (± 3.32)		
PI, Week 12, n=50, 52	43.7 (± 3.25)	43.8 (± 3.56)		
PI, Week 16, n=48, 53	43.8 (± 3.19)	43.4 (± 3.36)		
PI, Week 20, n=46, 53	43.6 (± 2.70)	43.3 (± 3.57)		
PI, Week 24, n=47, 53	43.5 (± 2.80)	43.3 (± 3.09)		
PI, Week 28, n=42, 53	43.5 (± 2.74)	42.8 (± 3.43)		
PI, Week 32, n=45, 51	43.2 (± 2.85)	43.7 (± 3.31)		
PI, Week 36, n=44, 50	43.5 (± 2.87)	43.4 (± 3.02)		
PI, Week 40, n=42, 51	44.2 (± 2.64)	43.9 (± 3.11)		
PI, Week 44, n=47, 51	43.6 (± 2.58)	43.9 (± 3.03)		

PI, Week 48, n=43, 50	43.9 (± 2.97)	44.5 (± 2.44)		
INI, Baseline, n=102, 99	44.3 (± 3.08)	44.9 (± 3.21)		
INI, Week 4, n=99, 97	43.9 (± 2.91)	43.8 (± 2.57)		
INI, Week 8, n=73, 98	43.7 (± 3.07)	43.9 (± 3.10)		
INI, Week 12, n=99, 95	44.1 (± 3.01)	44.3 (± 2.62)		
INI, Week 16, n=93, 96	43.9 (± 2.77)	43.7 (± 2.76)		
INI, Week 20, n=93, 97	43.6 (± 2.70)	44.1 (± 2.87)		
INI, Week 24, n=94, 95	43.4 (± 3.03)	43.9 (± 3.00)		
INI, Week 28, n=89, 93	44.0 (± 2.97)	43.9 (± 2.87)		
INI, Week 32, n=93, 95	44.1 (± 2.87)	43.7 (± 2.89)		
INI, Week 36, n=94, 95	43.6 (± 2.74)	43.7 (± 2.60)		
INI, Week 40, n=90, 95	44.1 (± 2.79)	43.6 (± 2.70)		
INI, Week 44, n=91, 94	43.6 (± 2.96)	43.8 (± 2.83)		
INI, Week 48, n=91, 95	44.3 (± 2.58)	44.3 (± 2.73)		
NNRTI, Baseline, n=155, 155	44.1 (± 3.11)	44.0 (± 3.10)		
NNRTI, Week 4, n=151, 153	43.4 (± 2.83)	43.7 (± 3.04)		
NNRTI, Week 8, n=122, 152	43.6 (± 2.96)	43.4 (± 3.16)		
NNRTI, Week 12, n=146, 152	43.3 (± 2.86)	43.7 (± 3.25)		
NNRTI, Week 16, n=143, 149	43.3 (± 2.61)	43.3 (± 3.27)		
NNRTI, Week 20, n=138, 152	43.1 (± 2.75)	43.2 (± 2.98)		
NNRTI, Week 24, n=143, 151	43.4 (± 2.54)	43.4 (± 3.01)		
NNRTI, Week 28, n=136, 150	43.3 (± 2.78)	43.2 (± 3.03)		
NNRTI, Week 32, n=137, 148	43.2 (± 2.74)	43.1 (± 3.43)		
NNRTI, Week 36, n=135, 147	43.0 (± 2.86)	43.3 (± 3.37)		
NNRTI, Week 40, n=138, 147	43.3 (± 2.66)	43.1 (± 3.20)		
NNRTI, Week 44, n=137, 148	43.7 (± 2.74)	43.2 (± 3.13)		
NNRTI, Week 48, n=131, 147	43.4 (± 2.73)	43.6 (± 3.14)		

Notes:

[99] - Safety Population

[100] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Bilirubin, direct bilirubin and creatinine

End point title	Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Bilirubin, direct bilirubin and creatinine

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: bilirubin, direct bilirubin and creatinine to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[101]	308[102]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
PI, Bilirubin, Baseline, n=51, 54	18.3 (± 20.54)	13.9 (± 11.07)		
PI, Bilirubin, Week 4, n=51, 53	9.3 (± 3.81)	14.4 (± 10.37)		
PI, Bilirubin, Week 8, n=34, 53	8.9 (± 3.45)	14.2 (± 10.79)		
PI, Bilirubin, Week 12, n=50, 52	8.1 (± 3.44)	15.6 (± 11.70)		
PI, Bilirubin, Week 16, n=48, 53	8.7 (± 3.95)	14.7 (± 10.78)		
PI, Bilirubin, Week 20, n=46, 53	9.3 (± 3.60)	15.6 (± 14.96)		
PI, Bilirubin, Week 24, n=47, 53	9.5 (± 3.42)	16.8 (± 16.15)		
PI, Bilirubin, Week 28, n=42, 53	9.4 (± 4.29)	15.0 (± 12.75)		
PI, Bilirubin, Week 32, n=45, 51	9.7 (± 3.66)	17.1 (± 12.45)		
PI, Bilirubin, Week 36, n=44, 50	8.3 (± 3.17)	16.0 (± 14.09)		
PI, Bilirubin, Week 40, n=42, 51	9.2 (± 3.51)	17.9 (± 18.08)		
PI, Bilirubin, Week 44, n=47, 51	9.5 (± 3.41)	18.1 (± 16.62)		
PI, Bilirubin, Week 48, n=43, 50	9.3 (± 3.77)	16.7 (± 10.73)		
INI, Bilirubin, Baseline, n=102, 99	9.4 (± 3.94)	9.7 (± 5.07)		
INI, Bilirubin, Week 4, n=99, 97	9.5 (± 3.88)	9.0 (± 4.77)		
INI, Bilirubin, Week 8, n=73, 98	10.1 (± 4.29)	10.7 (± 12.28)		
INI, Bilirubin, Week 12, n=99, 95	9.9 (± 4.50)	9.2 (± 3.91)		
INI, Bilirubin, Week 16, n=93, 96	9.8 (± 4.29)	9.6 (± 3.80)		
INI, Bilirubin, Week 20, n=93, 97	10.1 (± 4.05)	9.3 (± 3.60)		
INI, Bilirubin, Week 24, n=94, 94	9.4 (± 4.11)	9.1 (± 3.81)		
INI, Bilirubin, Week 28, n=89, 93	10.3 (± 3.53)	9.5 (± 4.67)		
INI, Bilirubin, Week 32, n=93, 95	9.9 (± 4.42)	8.8 (± 3.32)		
INI, Bilirubin, Week 36, n=94, 95	9.8 (± 4.09)	9.1 (± 3.76)		
INI, Bilirubin, Week 40, n=90, 95	9.9 (± 4.12)	8.9 (± 3.63)		
INI, Bilirubin, Week 44, n=91, 94	10.1 (± 4.75)	9.0 (± 3.40)		
INI, Bilirubin, Week 48, n=91, 95	10.3 (± 4.37)	8.9 (± 3.76)		
NNRTI, Bilirubin, Baseline, n=155, 155	7.4 (± 3.30)	7.2 (± 3.30)		
NNRTI, Bilirubin, Week 4, n=151, 153	8.7 (± 4.10)	6.9 (± 2.98)		
NNRTI, Bilirubin, Week 8, n=122, 152	8.9 (± 4.01)	6.8 (± 3.40)		
NNRTI, Bilirubin, Week 12, n=146, 152	9.3 (± 4.66)	7.1 (± 3.50)		
NNRTI, Bilirubin, Week 16, n=143, 149	10.5 (± 14.51)	6.8 (± 3.52)		
NNRTI, Bilirubin, Week 20, n=138, 152	9.6 (± 4.63)	7.1 (± 3.15)		
NNRTI, Bilirubin, Week 24, n=143, 151	9.1 (± 3.93)	6.9 (± 3.75)		
NNRTI, Bilirubin, Week 28, n=136, 150	9.7 (± 4.17)	6.9 (± 3.29)		
NNRTI, Bilirubin, Week 32, n=137, 148	9.7 (± 4.55)	6.9 (± 3.52)		
NNRTI, Bilirubin, Week 36, n=135, 147	9.3 (± 3.72)	7.0 (± 3.33)		
NNRTI, Bilirubin, Week 40, n=138, 147	9.6 (± 4.21)	7.0 (± 3.43)		
NNRTI, Bilirubin, Week 44, n=137, 148	9.4 (± 4.03)	7.1 (± 3.25)		
NNRTI, Bilirubin, Week 48, n=131, 147	9.4 (± 4.28)	7.3 (± 3.19)		
PI, Direct bilirubin, Baseline, n=51, 54	3.6 (± 2.13)	2.9 (± 1.68)		
PI, Direct bilirubin, Week 4, n=51, 53	2.4 (± 1.20)	3.3 (± 1.67)		
PI, Direct bilirubin, Week 8, n=34, 53	2.3 (± 1.12)	2.8 (± 1.68)		
PI, Direct bilirubin, Week 12, n=50, 52	1.9 (± 0.80)	3.2 (± 1.95)		
PI, direct bilirubin, Week 16, n=48, 53	2.0 (± 0.87)	2.9 (± 1.45)		
PI, Direct bilirubin, Week 20, n=46, 53	2.2 (± 0.79)	2.9 (± 2.17)		
PI, Direct bilirubin, Week 24, n=47, 53	2.2 (± 0.75)	3.1 (± 2.02)		

PI, Direct bilirubin, Week 28, n=42, 53	2.1 (± 1.08)	2.7 (± 1.84)		
PI, Direct bilirubin, Week 32, n=45, 51	2.2 (± 0.88)	3.1 (± 1.84)		
PI, Direct bilirubin, Week 36, n=44, 50	1.9 (± 0.80)	3.1 (± 1.95)		
PI, Direct bilirubin, Week 40, n=42, 51	2.0 (± 0.77)	3.2 (± 2.05)		
PI, Direct bilirubin, Week 44, n=47, 51	2.1 (± 0.83)	3.3 (± 1.99)		
PI, Direct bilirubin, Week 48, n=43, 50	2.3 (± 0.93)	3.2 (± 1.71)		
INI, Direct bilirubin, Baseline, n=102, 99	2.4 (± 0.96)	2.3 (± 1.16)		
INI, Direct bilirubin, Week 4, n=99, 97	2.4 (± 0.90)	2.3 (± 1.18)		
INI, Direct bilirubin, Week 8, n=73, 98	2.4 (± 1.02)	3.0 (± 6.70)		
INI, Direct bilirubin, Week 12, n=99, 95	2.3 (± 0.98)	2.3 (± 1.06)		
INI, Direct bilirubin, Week 16, n=93, 96	2.3 (± 1.03)	2.1 (± 0.87)		
INI, Direct bilirubin, Week 20, n=93, 97	2.2 (± 0.85)	2.1 (± 0.89)		
INI, Direct bilirubin, Week 24, n=94, 94	2.2 (± 1.02)	2.0 (± 0.78)		
INI, Direct bilirubin, Week 28, n=89, 93	2.2 (± 0.74)	2.1 (± 1.12)		
INI, Direct bilirubin, Week 32, n=93, 95	2.2 (± 0.94)	1.9 (± 0.77)		
INI, Direct bilirubin, Week 36, n=94, 95	2.2 (± 1.25)	2.0 (± 0.97)		
INI, Direct bilirubin, Week 40, n=90, 95	2.2 (± 1.06)	2.0 (± 1.11)		
INI, Direct bilirubin. Week 44, n=91, 94	2.3 (± 0.99)	2.1 (± 0.95)		
INI, Direct bilirubin, Week 48, n=91, 95	2.3 (± 0.82)	2.2 (± 1.00)		
NNRTI, Direct bilirubin, Baseline, n=155, 155	2.1 (± 1.00)	1.9 (± 1.00)		
NNRTI, Direct bilirubin, Week 4, n=151, 153	2.2 (± 1.06)	2.0 (± 0.96)		
NNRTI, Direct bilirubin, Week 8, n=122, 152	2.2 (± 1.10)	1.9 (± 0.97)		
NNRTI, Direct bilirubin, Week 12, n=146, 152	2.2 (± 1.12)	1.9 (± 0.98)		
NNRTI, Direct bilirubin, Week 16, n=143, 149	2.7 (± 6.95)	1.9 (± 0.90)		
NNRTI, Direct bilirubin, Week 20, n=138, 152	2.2 (± 1.07)	1.7 (± 0.97)		
NNRTI, Week 24, Direct bilirubin, n=143, 151	2.1 (± 1.04)	1.8 (± 0.95)		
NNRTI, Direct bilirubin, Week 28, n=136, 150	2.1 (± 1.01)	1.7 (± 1.01)		
NNRTI, Direct bilirubin, Week 32, n=137, 148	2.1 (± 1.08)	1.7 (± 0.94)		
NNRTI, Direct bilirubin, Week 36, n=135, 147	2.1 (± 1.10)	1.7 (± 0.94)		
NNRTI, Direct bilirubin, Week 40, n=138, 147	2.1 (± 1.18)	1.7 (± 1.00)		
NNRTI, Direct bilirubin, Week 44, n=137, 148	2.1 (± 0.96)	1.8 (± 0.91)		
NNRTI, Direct bilirubin, Week 48, n=131, 147	2.2 (± 0.98)	1.9 (± 0.96)		
PI, Creatinine, Baseline, n=51, 54	71.41 (± 12.315)	70.20 (± 13.391)		
PI, Creatinine, Week 4, n=51, 53	72.87 (± 11.632)	72.53 (± 14.574)		
PI, Creatinine, Week 8, n=34, 53	71.66 (± 13.012)	71.54 (± 14.362)		
PI, Creatinine, Week 12, n=50, 52	70.05 (± 11.609)	73.22 (± 14.968)		
PI, Creatinine, Week 16, n=48, 53	71.05 (± 11.778)	73.25 (± 15.740)		
PI, Creatinine, Week 20, n=46, 53	73.40 (± 12.191)	75.37 (± 15.799)		

PI, Creatinine, Week 24, n=47, 53	72.75 (± 11.654)	72.84 (± 14.549)		
PI, Creatinine, Week 28, n=42, 53	75.18 (± 13.118)	73.42 (± 14.738)		
PI, Creatinine, Week 32, n=45, 51	74.59 (± 13.730)	73.93 (± 15.399)		
PI, Creatinine, Week 36, n=44, 50	74.41 (± 12.217)	72.37 (± 14.570)		
PI, Creatinine, Week 40, n=42, 51	74.31 (± 11.749)	73.73 (± 15.726)		
PI, Creatinine, Week 44, n=47, 51	75.38 (± 13.405)	73.00 (± 14.885)		
PI, Creatinine, Week 48, n=43, 50	76.95 (± 13.021)	72.21 (± 15.031)		
INI, Creatinine, Baseline, n=102, 99	88.16 (± 16.835)	86.34 (± 17.320)		
INI, Creatinine, Week 4, n=99, 95	86.39 (± 14.472)	87.66 (± 16.208)		
INI, Creatinine, Week 8, n=73, 98	85.52 (± 15.851)	88.11 (± 17.308)		
INI, Creatinine, Week 12, n=99, 95	85.53 (± 17.539)	89.36 (± 17.923)		
INI, Creatinine, Week 16, n=93, 96	84.99 (± 15.429)	86.85 (± 17.320)		
INI, Creatinine, Week 20, n=93, 97	85.01 (± 14.695)	87.06 (± 16.987)		
INI, Creatinine, Week 24, n=94, 94	84.21 (± 15.039)	87.02 (± 16.777)		
INI, Creatinine, Week 28, n=89, 93	84.84 (± 15.670)	87.41 (± 17.065)		
INI, Creatinine, Week 32, n=93, 95	85.42 (± 15.349)	86.91 (± 15.628)		
INI, Creatinine, Week 36, n=94, 95	84.49 (± 15.189)	87.20 (± 15.835)		
INI, Creatinine, Week 40, n=90, 95	85.92 (± 14.651)	87.70 (± 17.119)		
INI, Creatinine, Week 44, n=91, 94	84.66 (± 15.701)	87.08 (± 16.694)		
INI, Creatinine, Week 48, n=91, 95	85.27 (± 15.683)	86.64 (± 15.958)		
NNRTI, Creatinine, Baseline, n=155, 155	75.57 (± 14.604)	75.06 (± 14.671)		
NNRTI, Creatinine, Week 4, n=151, 153	78.57 (± 15.814)	76.79 (± 14.908)		
NNRTI, Creatinine, Week 8, n=122, 152	76.75 (± 15.759)	76.17 (± 14.876)		
NNRTI, Creatinine, Week 12, n=146, 152	76.93 (± 15.495)	75.50 (± 14.723)		
NNRTI, Creatinine, Week 16, n=143, 149	77.22 (± 15.406)	77.00 (± 16.025)		
NNRTI, Creatinine, Week 20, n=138, 152	78.32 (± 16.372)	76.36 (± 15.744)		
NNRTI, Creatinine, Week 24, n=143, 151	79.92 (± 21.430)	76.26 (± 15.534)		
NNRTI, Creatinine, Week 28, n=136, 150	79.13 (± 17.039)	76.45 (± 15.060)		
NNRTI, Creatinine, Week 32, n=137, 148	77.40 (± 14.117)	77.05 (± 16.200)		
NNRTI, Creatinine, Week 36, n=135, 147	78.15 (± 16.839)	76.64 (± 15.734)		
NNRTI, Creatinine, Week 40, n=138, 147	78.42 (± 16.662)	76.04 (± 15.083)		

NNRTI, Creatinine, Week 44, n=137, 148	78.45 (± 15.909)	76.25 (± 15.257)		
NNRTI, Creatinine, Week 48, n=131, 147	78.91 (± 17.389)	75.67 (± 14.794)		

Notes:

[101] - Safety Population

[102] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Creatinine clearance

End point title	Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Creatinine clearance

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: creatinine clearance to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). GFR will be estimated by the central laboratory using the CKD-EPI. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[103]	308[104]		
Units: Milliliters per minute per 1.73meter^2				
arithmetic mean (standard deviation)				
PI, Baseline, n=51, 54	105.2 (± 15.67)	104.9 (± 15.22)		
PI, Week 4, n=51, 53	103.0 (± 15.59)	102.1 (± 15.68)		
PI, Week 8, n=34, 53	104.3 (± 14.52)	103.5 (± 15.61)		
PI, Week 12, n=50, 52	107.1 (± 14.95)	101.1 (± 15.94)		
PI, Week 16, n=48, 53	105.4 (± 15.88)	101.8 (± 15.99)		
PI, Week 20, n=46, 53	102.9 (± 17.17)	99.8 (± 16.53)		
PI, Week 24, n=47, 53	103.3 (± 14.64)	101.0 (± 15.54)		
PI, Week 28, n=42, 53	100.6 (± 16.62)	100.8 (± 14.58)		
PI, Week 32, n=45, 51	101.0 (± 17.38)	100.4 (± 16.04)		
PI, Week 36, n=44, 50	100.7 (± 16.68)	101.7 (± 14.42)		
PI, Week 40, n=42, 51	100.2 (± 14.54)	100.3 (± 15.51)		

PI, Week 44, n=47, 51	99.8 (± 18.00)	101.0 (± 15.31)		
PI, Week 48, n=43, 50	98.8 (± 17.31)	102.2 (± 15.45)		
INI, Baseline, n=102, 99	92.3 (± 17.62)	94.9 (± 18.82)		
INI, Week 4, n=99, 95	93.4 (± 15.07)	93.1 (± 18.22)		
INI, Week 8, n=72, 98	94.4 (± 17.05)	93.0 (± 18.12)		
INI, Week 12, n=99, 93	94.5 (± 16.82)	91.6 (± 18.81)		
INI, Week 16, n=93, 96	94.9 (± 16.02)	94.4 (± 18.30)		
INI, Week 20, n=93, 97	95.3 (± 15.97)	93.3 (± 17.48)		
INI, Week 24, n=94, 94	95.6 (± 15.88)	93.1 (± 17.21)		
INI, Week 28, n=89, 93	95.4 (± 17.00)	93.6 (± 17.89)		
INI, Week 32, n=92, 95	94.8 (± 17.16)	93.1 (± 16.94)		
INI, Week 36, n=94, 95	95.6 (± 15.81)	92.7 (± 15.65)		
INI, Week 40, n=89, 95	94.8 (± 16.32)	92.9 (± 18.15)		
INI, Week 44, n=91, 94	94.8 (± 15.64)	93.4 (± 17.94)		
INI, Week 48, n=90, 94	95.4 (± 16.20)	93.5 (± 17.00)		
NNRTI, Baseline, n=155, 155	104.4 (± 17.78)	103.7 (± 16.85)		
NNRTI, Week 4, n=151, 153	100.8 (± 18.35)	101.5 (± 17.72)		
NNRTI, Week 8, n=121, 152	102.3 (± 17.23)	102.2 (± 16.85)		
NNRTI, Week 12, n=146, 152	103.1 (± 18.02)	103.2 (± 17.47)		
NNRTI, Week 16, n=143, 148	102.5 (± 17.66)	101.0 (± 18.66)		
NNRTI, Week 20, n=138, 152	101.0 (± 17.94)	101.8 (± 17.61)		
NNRTI, Week 24, n=142, 151	99.6 (± 18.18)	101.7 (± 17.43)		
NNRTI, Week 28, n=136, 150	99.9 (± 18.23)	101.7 (± 17.20)		
NNRTI, Week 32, n=137, 148	101.3 (± 16.10)	101.0 (± 17.79)		
NNRTI, Week 36, n=135, 147	100.8 (± 18.02)	101.4 (± 17.46)		
NNRTI, Week 40, n=137, 147	100.5 (± 18.40)	101.6 (± 16.68)		
NNRTI, Week 44, n=136, 148	99.9 (± 17.23)	101.8 (± 16.96)		
NNRTI, Week 48, n=131, 147	98.7 (± 17.35)	102.1 (± 16.83)		

Notes:

[103] - Safety Population

[104] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Lipase

End point title	Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Lipase

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: lipase to assess the

impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[105]	308[106]		
Units: Units per liter				
arithmetic mean (standard deviation)				
PI, Baseline, n=51, 54	27.6 (± 21.69)	33.0 (± 22.44)		
PI, Week 4, n=51, 53	25.5 (± 14.41)	34.4 (± 20.77)		
PI, Week 8, n=34, 53	23.4 (± 10.96)	35.7 (± 28.85)		
PI, Week 12, n=49, 52	26.4 (± 12.00)	31.2 (± 15.31)		
PI, Week 16, n=47, 53	28.1 (± 13.01)	34.6 (± 18.14)		
PI, Week 20, n=46, 53	25.8 (± 11.37)	32.7 (± 16.37)		
PI, Week 24, n=47, 53	25.8 (± 11.74)	30.5 (± 15.48)		
PI, Week 28, n=42, 53	26.4 (± 10.86)	33.4 (± 15.92)		
PI, Week 32, n=45, 51	26.9 (± 12.18)	36.2 (± 24.23)		
PI, Week 36, n=44, 50	27.1 (± 13.69)	32.7 (± 17.14)		
PI, Week 40, n=42, 51	30.5 (± 19.78)	32.0 (± 15.16)		
PI, Week 44, n=47, 51	27.1 (± 10.70)	35.2 (± 18.59)		
PI, Week 48, n=43, 50	26.3 (± 12.02)	32.7 (± 15.62)		
INI, Baseline, n=102, 99	29.3 (± 20.90)	28.2 (± 16.64)		
INI, Week 4, n=99, 97	36.8 (± 43.46)	32.1 (± 31.31)		
INI, Week 8, n=72, 98	28.8 (± 16.80)	27.7 (± 12.72)		
INI, Week 12, n=99, 93	33.1 (± 20.98)	29.8 (± 23.81)		
INI, Week 16, n=93, 97	34.4 (± 33.09)	28.9 (± 14.77)		
INI, Week 20, n=94, 97	32.0 (± 28.19)	29.1 (± 16.34)		
INI, Week 24, n=94, 95	32.0 (± 19.15)	30.1 (± 21.56)		
INI, Week 28, n=89, 94	35.1 (± 38.32)	32.8 (± 24.85)		
INI, Week 32, n=92, 95	32.6 (± 23.00)	32.7 (± 21.75)		
INI, Week 36, n=94, 95	35.0 (± 32.32)	27.6 (± 12.20)		
INI, Week 40, n=89, 95	33.8 (± 20.14)	29.6 (± 14.21)		
INI, Week 44, n=91, 94	34.6 (± 34.66)	32.8 (± 22.45)		
INI, Week 48, n=90, 94	35.1 (± 36.88)	31.6 (± 23.18)		
NNRTI, Baseline, n=155, 155	32.1 (± 24.46)	31.8 (± 19.30)		
NNRTI, Week 4, n=151, 153	37.6 (± 64.95)	31.7 (± 17.60)		
NNRTI, Week 8, n=121, 152	33.8 (± 27.26)	33.4 (± 21.17)		
NNRTI, Week 12, n=146, 152	35.6 (± 34.76)	29.7 (± 14.64)		
NNRTI, Week 16, n=145, 149	35.3 (± 32.66)	36.8 (± 46.27)		
NNRTI, Week 20, n=138, 152	32.0 (± 19.03)	32.9 (± 37.34)		
NNRTI, Week 24, n=142, 151	36.2 (± 29.08)	37.2 (± 36.77)		
NNRTI, Week 28, n=136, 150	33.4 (± 21.71)	33.1 (± 17.20)		
NNRTI, Week 32, n=137, 148	40.6 (± 83.20)	33.6 (± 20.70)		
NNRTI, Week 36, n=135, 147	39.9 (± 67.63)	33.9 (± 21.66)		
NNRTI, Week 40, n=138, 147	38.6 (± 46.34)	32.3 (± 16.96)		

NNRTI, Week 44, n=136, 148	34.5 (± 23.27)	32.9 (± 19.81)		
NNRTI, Week 48, n=131, 146	36.3 (± 30.60)	32.8 (± 20.04)		

Notes:

[105] - Safety Population

[106] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48

End point title	Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: CO2, chloride, glucose, phosphate, potassium, sodium and urea to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[107]	308[108]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
PI, CO2, Baseline, n=51, 54	22.3 (± 2.53)	22.7 (± 2.17)		
PI, CO2, Week 4, n=51, 53	23.6 (± 2.37)	23.4 (± 2.28)		
PI, CO2, Week 8, n=34, 53	23.0 (± 1.95)	23.0 (± 2.53)		
PI, CO2, Week 12, n=50, 52	22.9 (± 2.14)	22.9 (± 2.41)		
PI, CO2, Week 16, n=48, 53	23.0 (± 2.07)	22.9 (± 2.32)		
PI, CO2, Week 20, n=46, 53	23.1 (± 2.04)	22.7 (± 2.59)		
PI, CO2, Week 24, n=47, 53	22.7 (± 1.95)	22.8 (± 2.62)		
PI, CO2, Week 28, n=42, 53	22.7 (± 2.31)	22.5 (± 2.48)		
PI, CO2, Week 32, n=45, 51	22.6 (± 2.22)	22.6 (± 2.84)		
PI, CO2, Week 36, n=44, 50	22.6 (± 2.21)	22.4 (± 2.36)		
PI, CO2, Week 40, n=42, 51	22.8 (± 2.24)	23.1 (± 2.37)		
PI, CO2, Week 44, n=47, 51	22.9 (± 1.94)	23.1 (± 2.37)		
PI, CO2, Week 48, n=43, 50	23.0 (± 2.01)	22.7 (± 2.19)		
INI, CO2, Baseline, n=102, 99	22.8 (± 2.09)	22.9 (± 2.08)		
INI, CO2, Week 4, n=99, 97	23.7 (± 2.36)	23.7 (± 2.28)		
INI, CO2, Week 8, n=73, 98	23.0 (± 2.10)	23.6 (± 2.20)		
INI, CO2, Week 12, n=99, 95	23.2 (± 2.07)	23.3 (± 2.26)		
INI, CO2, Week 16, n=93, 96	22.8 (± 2.10)	23.5 (± 2.39)		
INI, CO2, Week 20, n=93, 97	22.8 (± 2.11)	23.6 (± 2.14)		
INI, CO2, Week 24, n=94, 95	22.8 (± 2.22)	23.1 (± 2.21)		

INI, CO2, Week 28, n=89, 93	22.5 (± 2.21)	23.1 (± 2.14)		
INI, CO2, Week 32, n=93, 95	22.8 (± 2.17)	23.0 (± 2.09)		
INI, CO2, Week 36, n=94, 95	22.8 (± 1.90)	23.5 (± 2.12)		
INI, CO2, Week 40, n=90, 95	23.1 (± 2.07)	23.2 (± 2.09)		
INI, CO2, Week 44, n=91, 94	23.1 (± 2.08)	23.7 (± 2.11)		
INI, CO2, Week 48, n=91, 95	22.9 (± 1.97)	23.3 (± 2.32)		
NNRTI, CO2, Baseline, n=155, 155	22.7 (± 2.41)	22.3 (± 2.35)		
NNRTI, CO2, Week 4, n=151, 153	23.7 (± 2.63)	23.0 (± 2.24)		
NNRTI, CO2, Week 8, n=122, 152	23.2 (± 2.28)	23.1 (± 2.61)		
NNRTI, CO2, Week 12, n=146, 152	23.2 (± 2.18)	22.8 (± 2.39)		
NNRTI, CO2, Week 16, n=143, 149	23.0 (± 2.24)	22.8 (± 2.23)		
NNRTI, CO2, Week 20, n=138, 152	22.9 (± 2.24)	22.5 (± 2.20)		
NNRTI, CO2, Week 24, n=143, 150	23.0 (± 2.49)	22.7 (± 2.45)		
NNRTI, CO2, Week 28, n=136, 150	22.8 (± 2.58)	22.6 (± 2.27)		
NNRTI, CO2, Week 32, n=137, 148	22.5 (± 2.11)	22.7 (± 2.29)		
NNRTI, CO2, Week 36, n=135, 147	22.8 (± 2.38)	22.8 (± 2.27)		
NNRTI, CO2, Week 40, n=138, 147	23.1 (± 2.40)	22.8 (± 2.68)		
NNRTI, CO2, Week 44, n=137, 148	23.0 (± 2.35)	22.8 (± 2.38)		
NNRTI, CO2, Week 48, n=131, 147	22.5 (± 2.55)	22.6 (± 2.29)		
PI, Chloride, Baseline, n=51, 54	104.0 (± 1.46)	103.5 (± 2.61)		
PI, Chloride, Week 4, n=51, 53	104.5 (± 1.80)	104.0 (± 2.10)		
PI, Chloride, Week 8, n=34, 53	104.4 (± 2.35)	104.2 (± 2.28)		
PI, Chloride, Week 12, n=50, 52	104.4 (± 2.02)	104.3 (± 2.13)		
PI, Chloride, Week 16, n=48, 53	104.4 (± 2.08)	104.5 (± 2.10)		
PI, Chloride, Week 20, n=46, 53	104.8 (± 1.98)	104.2 (± 1.97)		
PI, Chloride, Week 24, n=47, 53	105.1 (± 1.85)	104.7 (± 2.02)		
PI, Chloride, Week 28, n=42, 53	105.3 (± 1.88)	104.6 (± 2.47)		
PI, Chloride, Week 32, n=45, 51	105.0 (± 2.32)	104.4 (± 1.92)		
PI, Chloride, Week 36, n=44, 50	105.0 (± 2.17)	104.4 (± 2.27)		
PI, Chloride, Week 40, n=42, 51	105.2 (± 2.27)	104.5 (± 2.31)		
PI, Chloride, Week 44, n=47, 51	105.1 (± 1.84)	104.5 (± 1.88)		
PI, Chloride, Week 48, n=43, 50	104.4 (± 1.72)	104.3 (± 1.88)		
INI, Chloride, Baseline, n=102, 99	103.6 (± 2.03)	103.5 (± 2.26)		
INI, Chloride, Week 4, n=99, 97	104.0 (± 2.17)	104.0 (± 2.15)		
INI, Chloride, Week 8, n=73, 98	104.1 (± 2.16)	103.5 (± 2.58)		
INI, Chloride, Week 12, n=99, 95	104.1 (± 2.31)	104.0 (± 2.32)		
INI, Chloride, Week 16, n=93, 96	104.7 (± 2.05)	104.2 (± 2.26)		
INI, Chloride, Week 20, n=93, 97	104.8 (± 2.39)	103.8 (± 2.36)		
INI, Chloride, Week 24, n=94, 95	104.3 (± 2.30)	104.1 (± 2.50)		
INI, Chloride, Week 28, n=89, 93	104.7 (± 1.92)	104.0 (± 2.16)		
INI, Chloride, Week 32, n=93, 95	104.5 (± 2.33)	104.2 (± 2.47)		
INI, Chloride, Week 36, n=94, 95	104.6 (± 2.04)	104.1 (± 2.40)		
INI, Chloride, Week 40, n=90, 95	104.4 (± 1.94)	103.9 (± 2.48)		
INI, Chloride, Week 44, n=91, 94	104.5 (± 2.12)	104.0 (± 2.27)		
INI, Chloride, Week 48, n=91, 95	104.2 (± 2.43)	103.2 (± 2.26)		
NNRTI, Chloride, Baseline, n=155, 155	103.9 (± 2.18)	104.0 (± 2.37)		
NNRTI, Chloride, Week 4, n=151, 153	104.3 (± 2.21)	104.6 (± 2.29)		
NNRTI, Chloride, Week 8, n=122, 152	104.4 (± 2.31)	104.7 (± 2.22)		
NNRTI, Chloride, Week 12, n=146, 152	104.3 (± 2.33)	104.5 (± 2.23)		
NNRTI, Chloride, Week 16, n=143, 149	104.4 (± 2.37)	104.8 (± 2.34)		
NNRTI, Chloride, Week 20, n=138, 152	104.6 (± 2.55)	105.1 (± 2.38)		
NNRTI, Chloride, Week 24, n=143, 151	104.4 (± 2.52)	105.1 (± 2.18)		

NNRTI, Chloride, Week 28, n=136, 150	104.7 (± 2.41)	105.3 (± 2.31)		
NNRTI, Chloride, Week 32, n=137, 148	104.7 (± 2.68)	105.1 (± 2.26)		
NNRTI, Chloride, Week 36, n=135, 147	105.0 (± 2.28)	105.1 (± 2.30)		
NNRTI, Chloride, Week 40, n=138, 147	104.7 (± 2.36)	105.0 (± 2.70)		
NNRTI, Chloride, Week 44, n=137, 148	104.6 (± 2.17)	105.0 (± 2.32)		
NNRTI, Chloride, Week 48, n=131, 147	104.6 (± 2.54)	104.5 (± 2.46)		
PI, Glucose, Baseline, n=51, 53	5.11 (± 0.878)	5.03 (± 0.505)		
PI, Glucose, Week 4, n=43, 43	5.06 (± 0.481)	5.29 (± 0.452)		
PI, Glucose, Week 8, n=25, 41	5.11 (± 0.456)	5.18 (± 0.462)		
PI, Glucose, Week 12, n=40, 43	5.21 (± 0.533)	5.25 (± 0.535)		
PI, Glucose, Week 16, n=39, 44	5.24 (± 0.800)	5.26 (± 0.614)		
PI, Glucose, Week 20, n=35, 42	5.11 (± 0.580)	5.29 (± 0.718)		
PI, Glucose, Week 24, n=38, 43	5.31 (± 0.526)	5.29 (± 0.747)		
PI, Glucose, Week 28, n=32, 43	5.16 (± 0.651)	5.12 (± 0.512)		
PI, Glucose, Week 32, n=36, 42	5.37 (± 0.700)	5.31 (± 0.643)		
PI, Glucose, Week 36, n=35, 42	5.13 (± 0.525)	5.23 (± 0.513)		
PI, Glucose, Week 40, n=34, 41	5.31 (± 0.464)	5.17 (± 0.555)		
PI, Glucose, Week 44, n=40, 40	5.13 (± 0.681)	5.20 (± 0.408)		
PI, Glucose, Week 48, n=39, 48	5.16 (± 0.647)	5.18 (± 0.661)		
INI, Glucose, Baseline, n=98, 96	5.06 (± 0.638)	5.25 (± 0.801)		
INI, Glucose, Week 4, n=55, 54	5.39 (± 0.771)	5.37 (± 1.043)		
INI, Glucose, Week 8, n=36, 58	5.16 (± 0.584)	5.49 (± 1.307)		
INI, Glucose, Week 12, n=53, 56	5.50 (± 1.317)	5.51 (± 1.414)		
INI, Glucose, Week 16, n=54, 53	5.41 (± 1.727)	5.25 (± 0.624)		
INI, Glucose, Week 20, n=52, 58	5.36 (± 0.674)	5.21 (± 0.793)		
INI, Glucose, Week 24, n=61, 62	5.34 (± 0.660)	5.36 (± 0.753)		
INI, Glucose, Week 28, n=53, 63	5.32 (± 0.817)	5.45 (± 0.940)		
INI, Glucose, Week 32, n=54, 56	5.57 (± 1.260)	5.52 (± 0.839)		
INI, Glucose, Week 36, n=53, 58	5.46 (± 0.697)	5.34 (± 1.142)		
INI, Glucose, Week 40, n=59, 63	5.53 (± 0.931)	5.46 (± 0.765)		
INI, Glucose, Week 44, n=54, 57	5.40 (± 1.020)	5.43 (± 0.637)		
INI, Glucose, Week 48, n=84, 91	5.16 (± 0.549)	5.24 (± 0.752)		
NNRTI, Glucose, Baseline, n=152, 150	4.93 (± 0.697)	5.17 (± 1.201)		
NNRTI, Glucose, Week 4, n=118, 129	5.11 (± 0.798)	5.48 (± 1.490)		
NNRTI, Glucose, Week 8, n=92, 119	5.17 (± 1.204)	5.35 (± 1.030)		
NNRTI, Glucose, Week 12, n=113, 122	5.04 (± 0.856)	5.30 (± 1.067)		
NNRTI, Glucose, Week 16, n=116, 119	5.12 (± 0.914)	5.45 (± 1.683)		
NNRTI, Glucose, Week 20, n=107, 121	5.16 (± 0.802)	5.48 (± 1.476)		
NNRTI, Glucose, Week 24, n=116, 124	5.16 (± 0.944)	5.36 (± 0.914)		
NNRTI, Glucose, Week 28, n=105, 120	5.08 (± 0.635)	5.40 (± 0.934)		
NNRTI, Glucose, Week 32, n=104, 121	5.18 (± 1.000)	5.47 (± 1.316)		
NNRTI, Glucose, Week 36, n=103, 120	5.07 (± 0.856)	5.49 (± 1.857)		
NNRTI, Glucose, Week 40, n=102, 114	5.16 (± 0.776)	5.53 (± 1.558)		
NNRTI, Glucose, Week 44, n=99, 116	5.15 (± 0.877)	5.53 (± 1.708)		
NNRTI, Glucose, Week 48, n=119, 138	5.01 (± 0.640)	5.23 (± 1.160)		
PI, Phosphate, Baseline, n=51, 54	1.048 (± 0.1523)	1.060 (± 0.1719)		
PI, Phosphate, Week 4, n=51, 53	1.116 (± 0.1648)	1.069 (± 0.1647)		
PI, Phosphate, Week 8, n=34, 53	1.119 (± 0.1891)	1.041 (± 0.1664)		
PI, Phosphate, Week 12, n=50, 52	1.073 (± 0.1788)	1.064 (± 0.1872)		

PI, Phosphate, Week 16, n=48, 53	1.111 (± 0.2006)	1.051 (± 0.1849)		
PI, Phosphate, Week 20, n=46, 53	1.119 (± 0.1689)	1.076 (± 0.2187)		
PI, Phosphate, Week 24, n=47, 53	1.086 (± 0.1647)	1.077 (± 0.1631)		
PI, Phosphate, Week 28, n=42, 53	1.085 (± 0.1803)	1.076 (± 0.1970)		
PI, Phosphate, Week 32, n=45, 51	1.109 (± 0.1869)	1.081 (± 0.1769)		
PI, Phosphate, Week 36, n=44, 50	1.084 (± 0.1659)	1.058 (± 0.1830)		
PI, Phosphate, Week 40, n=42, 51	1.067 (± 0.2020)	1.053 (± 0.1932)		
PI, Phosphate, Week 44, n=47, 51	1.084 (± 0.1785)	1.063 (± 0.2227)		
PI, Phosphate, Week 48, n=43, 50	1.095 (± 0.1636)	1.070 (± 0.1804)		
INI, Phosphate, Baseline, n=102, 99	1.045 (± 0.1687)	1.063 (± 0.1700)		
INI, Phosphate, Week 4, n=99, 97	1.080 (± 0.1725)	1.082 (± 0.1857)		
INI, Phosphate, Week 8, n=73, 98	1.086 (± 0.1901)	1.071 (± 0.2001)		
INI, Phosphate, Week 12, n=99, 95	1.068 (± 0.1970)	1.078 (± 0.1823)		
INI, Phosphate, Week 16, n=93, 96	1.063 (± 0.1623)	1.061 (± 0.1702)		
INI, Phosphate, Week 20, n=93, 97	1.046 (± 0.1717)	1.091 (± 0.1757)		
INI, Phosphate, Week 24, n=94, 95	1.066 (± 0.1661)	1.052 (± 0.1921)		
INI, Phosphate, Week 28, n=89, 93	1.060 (± 0.1602)	1.065 (± 0.1835)		
INI, Phosphate, Week 32, n=93, 95	1.045 (± 0.1649)	1.045 (± 0.1569)		
INI, Phosphate, Week 36, n=94, 95	1.032 (± 0.1572)	1.059 (± 0.1800)		
INI, Phosphate, Week 40, n=90, 95	1.054 (± 0.1838)	1.062 (± 0.1731)		
INI, Phosphate, Week 44, n=91, 94	1.043 (± 0.1805)	1.066 (± 0.2029)		
INI, Phosphate, Week 48, n=91, 95	1.072 (± 0.1721)	1.066 (± 0.1918)		
NNRTI, Phosphate, Baseline, n=155, 155	1.038 (± 0.1905)	1.040 (± 0.1741)		
NNRTI, Phosphate, Week 4, n=151, 153	1.128 (± 0.1867)	1.056 (± 0.1764)		
NNRTI, Phosphate, Week 8, n=122, 152	1.097 (± 0.1994)	1.024 (± 0.1784)		
NNRTI, Phosphate, Week 12, n=146, 152	1.091 (± 0.1838)	1.051 (± 0.2002)		
NNRTI, Phosphate, Week 16, n=143, 149	1.082 (± 0.1827)	1.046 (± 0.1700)		
NNRTI, Phosphate, Week 20, n=138, 152	1.076 (± 0.1763)	1.037 (± 0.1806)		
NNRTI, Phosphate, Week 24, n=143, 151	1.091 (± 0.1914)	1.052 (± 0.1882)		
NNRTI, Phosphate, Week 28, n=136, 150	1.076 (± 0.1764)	1.038 (± 0.1585)		
NNRTI, Phosphate, Week 32, n=137, 148	1.057 (± 0.1722)	1.050 (± 0.1874)		

NNRTI, Phosphate, Week 36, n=135, 147	1.055 (± 0.1790)	1.039 (± 0.1793)		
NNRTI, Phosphate, Week 40, n=138, 147	1.071 (± 0.1689)	1.033 (± 0.1724)		
NNRTI, Phosphate, Week 44, n=137, 148	1.076 (± 0.1795)	1.040 (± 0.1693)		
NNRTI, Phosphate, Week 48, n=131, 147	1.075 (± 0.1941)	1.037 (± 0.1789)		
PI, Potassium, Baseline, n=51, 54	4.13 (± 0.288)	4.10 (± 0.308)		
PI, Potassium, Week 4, n=51, 53	4.25 (± 0.355)	4.31 (± 0.395)		
PI, Potassium, Week 8, n=34, 53	4.18 (± 0.283)	4.19 (± 0.331)		
PI, Potassium, Week 12, n=50, 52	4.25 (± 0.335)	4.31 (± 0.364)		
PI, Potassium, Week 16, n=48, 53	4.16 (± 0.322)	4.30 (± 0.359)		
PI, Potassium, Week 20, n=46, 53	4.18 (± 0.291)	4.29 (± 0.314)		
PI, Potassium, Week 24, n=47, 53	4.15 (± 0.335)	4.30 (± 0.379)		
PI, Potassium, Week 28, n=42, 53	4.21 (± 0.342)	4.26 (± 0.348)		
PI, Potassium, Week 32, n=45, 51	4.15 (± 0.326)	4.31 (± 0.367)		
PI, Potassium, Week 36, n=44, 50	4.25 (± 0.345)	4.26 (± 0.378)		
PI, Potassium, Week 40, n=42, 51	4.23 (± 0.293)	4.26 (± 0.363)		
PI, Potassium, Week 44, n=47, 51	4.24 (± 0.348)	4.32 (± 0.375)		
PI, Potassium, Week 48, n=43, 50	4.15 (± 0.292)	4.12 (± 0.320)		
INI, Potassium, Baseline, n=102, 99	4.17 (± 0.245)	4.18 (± 0.289)		
INI, Potassium, Week 4, n=99, 97	4.20 (± 0.311)	4.26 (± 0.359)		
INI, Potassium, Week 8, n=73, 98	4.14 (± 0.306)	4.24 (± 0.462)		
INI, Potassium, Week 12, n=99, 95	4.19 (± 0.340)	4.18 (± 0.291)		
INI, Potassium, Week 16, n=93, 96	4.15 (± 0.317)	4.19 (± 0.297)		
INI, Potassium, Week 20, n=93, 97	4.20 (± 0.299)	4.18 (± 0.289)		
INI, Potassium, Week 24, n=94, 95	4.19 (± 0.304)	4.21 (± 0.304)		
INI, Potassium,Week 28, n=89, 93	4.19 (± 0.412)	4.22 (± 0.341)		
INI, Potassium, Week 32, n=93, 95	4.20 (± 0.358)	4.19 (± 0.307)		
INI, Potassium, Week 36, n=94, 95	4.19 (± 0.365)	4.23 (± 0.332)		
INI, Potassium, Week 40, n=90, 95	4.18 (± 0.332)	4.19 (± 0.297)		
INI, Potassium, Week 44, n=91, 94	4.18 (± 0.309)	4.17 (± 0.314)		
INI, Potassium, Week 48, n=91, 95	4.15 (± 0.266)	4.16 (± 0.305)		
NNRTI, Potassium, Baseline, n=155, 155	4.16 (± 0.302)	4.18 (± 0.331)		
NNRTI, Potassium, Week 4, n=151, 153	4.21 (± 0.287)	4.28 (± 0.333)		
NNRTI, Potassium, Week 8, n=122, 152	4.17 (± 0.295)	4.23 (± 0.366)		
NNRTI, Potassium, Week 12, n=146, 152	4.18 (± 0.322)	4.26 (± 0.341)		
NNRTI, Potassium, Week 16, n=143, 149	4.20 (± 0.313)	4.23 (± 0.320)		
NNRTI, Potassium,Week 20, n=138, 152	4.20 (± 0.326)	4.21 (± 0.337)		
NNRTI, Potassium, Week 24, n=143, 150	4.19 (± 0.259)	4.22 (± 0.341)		
NNRTI, Potassium, Week 28, n=136, 150	4.18 (± 0.301)	4.25 (± 0.434)		
NNRTI, Potassium, Week 32, n=137, 148	4.17 (± 0.388)	4.20 (± 0.349)		
NNRTI, Potassium, Week 36, n=135, 147	4.17 (± 0.289)	4.22 (± 0.343)		
NNRTI, Potassium, Week 40, n=138, 147	4.20 (± 0.283)	4.26 (± 0.321)		
NNRTI, Potassium, Week 44, n=137, 148	4.23 (± 0.324)	4.24 (± 0.374)		

NNRTI, Potassium, Week 48, n=131, 147	4.14 (± 0.271)	4.17 (± 0.352)		
PI, Sodium, Baseline, n=51, 54	138.9 (± 2.15)	138.7 (± 2.10)		
PI, Sodium, Week 4, n=51, 53	139.3 (± 1.64)	139.0 (± 2.08)		
PI, Sodium, Week 8, n=34, 53	139.6 (± 2.10)	139.0 (± 1.95)		
PI, Sodium, Week 12, n=50, 52	139.3 (± 1.76)	139.4 (± 2.03)		
PI, Sodium, Week 16, n=48, 53	139.4 (± 2.18)	139.0 (± 1.75)		
PI, Sodium, Week 20, n=46, 53	139.6 (± 1.71)	139.1 (± 1.97)		
PI, Sodium, Week 24, n=47, 53	139.4 (± 2.08)	139.1 (± 2.07)		
PI, Sodium, Week 28, n=42, 53	140.3 (± 1.59)	139.5 (± 2.49)		
PI, Sodium, Week 32, n=45, 51	139.4 (± 2.14)	139.3 (± 2.28)		
PI, Sodium, Week 36, n=44, 50	139.7 (± 1.63)	139.4 (± 2.32)		
PI, Sodium, Week 40, n=42, 51	139.8 (± 1.94)	139.4 (± 1.93)		
PI, Sodium, Week 44, n=47, 51	139.7 (± 1.78)	139.4 (± 2.09)		
PI, Sodium, Week 48, n=43, 50	139.8 (± 1.86)	139.6 (± 1.90)		
INI, Sodium, Baseline, n=102, 99	138.8 (± 1.62)	139.0 (± 1.67)		
INI, Sodium, Week 4, n=99, 97	139.2 (± 1.58)	139.1 (± 1.72)		
INI, Sodium, Week 8, n=73, 98	138.8 (± 2.00)	138.8 (± 1.79)		
INI, Sodium, Week 12, n=99, 95	139.1 (± 1.97)	139.0 (± 1.88)		
INI, Sodium, Week 16, n=93, 96	139.1 (± 1.87)	139.4 (± 1.89)		
INI, Sodium, Week 20, n=93, 97	139.4 (± 1.92)	139.2 (± 1.67)		
INI, Sodium, Week 24, n=94, 95	139.3 (± 1.86)	139.1 (± 1.91)		
INI, Sodium, Week 28, n=89, 93	139.4 (± 1.65)	138.8 (± 1.67)		
INI, Sodium, Week 32, n=93, 95	139.4 (± 1.63)	139.2 (± 1.68)		
INI, Sodium, Week 36, n=94, 95	139.2 (± 1.84)	139.4 (± 1.99)		
INI, Sodium, Week 40, n=90, 95	139.3 (± 2.01)	139.3 (± 1.83)		
INI, Sodium, Week 44, n=91, 94	139.3 (± 1.67)	139.4 (± 1.88)		
INI, Sodium, Week 48, n=91, 95	139.3 (± 1.98)	139.0 (± 1.76)		
NNRTI, Sodium, Baseline, n=155, 155	139.1 (± 2.00)	139.2 (± 1.68)		
NNRTI, Sodium, Week 4, n=151, 153	139.4 (± 1.79)	139.2 (± 1.90)		
NNRTI, Sodium, Week 8, n=122, 152	139.1 (± 1.91)	139.2 (± 1.76)		
NNRTI, Sodium, Week 12, n=146, 152	139.2 (± 1.78)	139.2 (± 1.77)		
NNRTI, Sodium, Week 16, n=143, 149	139.0 (± 1.99)	139.0 (± 2.06)		
NNRTI, Sodium, Week 20, n=138, 152	139.0 (± 1.87)	139.5 (± 1.83)		
NNRTI, Sodium, Week 24, n=143, 151	139.2 (± 1.83)	139.4 (± 1.94)		
NNRTI, Sodium, Week 28, n=136, 150	139.3 (± 1.84)	139.4 (± 1.99)		
NNRTI, Sodium, Week 32, n=137, 148	139.2 (± 1.68)	139.7 (± 1.75)		
NNRTI, Sodium, Week 36, n=135, 147	139.4 (± 1.80)	139.7 (± 2.19)		
NNRTI, Sodium, Week 40, n=138, 147	139.4 (± 1.87)	139.7 (± 2.06)		
NNRTI, Sodium, Week 44, n=137, 148	139.5 (± 1.88)	139.7 (± 1.92)		
NNRTI, Sodium, Week 48, n=131, 147	139.4 (± 1.93)	139.5 (± 1.82)		
PI, Urea, Baseline, n=51, 54	4.97 (± 1.409)	4.89 (± 1.316)		
PI, Urea, Week 4, n=51, 53	4.99 (± 1.210)	4.91 (± 1.455)		
PI, Urea, Week 8, n=34, 53	5.10 (± 1.353)	4.88 (± 1.447)		
PI, Urea, Week 12, n=50, 52	5.03 (± 1.368)	4.85 (± 1.480)		
PI, Urea, Week 16, n=48, 53	5.20 (± 1.295)	5.09 (± 1.754)		
PI, Urea, Week 20, n=46, 53	5.18 (± 1.216)	5.07 (± 1.535)		
PI, Urea, Week 24, n=47, 53	5.44 (± 1.587)	5.00 (± 1.414)		
PI, Urea, Week 28, n=42, 53	5.21 (± 1.358)	4.90 (± 1.530)		
PI, Urea, Week 32, n=45, 51	5.13 (± 1.135)	5.09 (± 1.482)		
PI, Urea, Week 36, n=44, 50	4.99 (± 1.310)	4.78 (± 1.411)		
PI, Urea, Week 40, n=42, 51	5.35 (± 1.227)	5.30 (± 1.758)		

PI, Urea, Week 44, n=47, 51	5.38 (± 1.483)	5.10 (± 1.517)		
PI, Urea, Week 48, n=43, 50	5.22 (± 1.469)	5.11 (± 1.489)		
INI, Urea, Baseline, n=102, 99	5.76 (± 1.528)	5.61 (± 1.894)		
INI, Urea, Week 4, n=99, 97	5.63 (± 1.471)	5.77 (± 1.676)		
INI, Urea, Week 8, n=73, 98	5.80 (± 1.617)	5.60 (± 1.607)		
INI, Urea, Week 12, n=99, 95	5.81 (± 1.536)	5.83 (± 1.724)		
INI, Urea, Week 16, n=93, 96	5.76 (± 1.577)	5.70 (± 1.574)		
INI, Urea, Week 20, n=93, 97	5.75 (± 1.640)	5.76 (± 1.580)		
INI, Urea, Week 24, n=94, 95	5.84 (± 1.578)	5.72 (± 1.774)		
INI, Urea, Week 28, n=89, 93	5.76 (± 1.593)	5.65 (± 1.435)		
INI, Urea, Week 32, n=93, 95	5.67 (± 1.537)	5.63 (± 1.477)		
INI, Urea, Week 36, n=94, 95	5.67 (± 1.670)	5.53 (± 1.456)		
INI, Urea, Week 40, n=90, 95	5.81 (± 1.669)	5.66 (± 1.593)		
INI, Urea, Week 44, n=91, 94	5.59 (± 1.607)	5.46 (± 1.368)		
INI, Urea, Week 48, n=91, 95	5.83 (± 1.654)	5.50 (± 1.468)		
NNRTI, Urea, Baseline, n=155, 155	4.96 (± 1.519)	5.10 (± 1.510)		
NNRTI, Urea, Week 4, n=151, 153	5.08 (± 1.556)	5.09 (± 1.426)		
NNRTI, Urea, Week 8, n=122, 152	5.09 (± 1.675)	5.10 (± 1.465)		
NNRTI, Urea, Week 12, n=146, 152	5.20 (± 1.684)	5.13 (± 1.583)		
NNRTI, Urea, Week 16, n=143, 149	5.03 (± 1.768)	5.34 (± 1.660)		
NNRTI, Urea, Week 20, n=138, 152	5.18 (± 1.709)	5.15 (± 1.713)		
NNRTI, Urea, Week 24, n=143, 151	5.29 (± 1.878)	5.26 (± 1.591)		
NNRTI, Urea, Week 28, n=136, 150	5.20 (± 1.931)	5.10 (± 1.537)		
NNRTI, Urea, Week 32, n=137, 148	5.38 (± 1.796)	5.14 (± 1.687)		
NNRTI, Urea, Week 36, n=135, 147	5.07 (± 1.719)	5.13 (± 1.493)		
NNRTI, Urea, Week 40, n=138, 147	5.30 (± 1.616)	5.07 (± 1.377)		
NNRTI, Urea, Week 44, n=137, 148	5.23 (± 1.489)	5.18 (± 1.613)		
NNRTI, Urea, Week 48, n=131, 147	5.32 (± 1.671)	5.06 (± 1.380)		

Notes:

[107] - Safety Population

[108] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for fasting lipid panel using baseline third agent treatment class overtime including Week 48

End point title	Absolute values for fasting lipid panel using baseline third agent treatment class overtime including Week 48

End point description:

Blood samples were collected for the analysis of fasting lipid panel: triglycerides, total cholesterol, HDL cholesterol and LDL cholesterol to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI).Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[109]	308[110]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
PI, Triglycerides, Baseline, n=46, 50	1.951 (± 1.8801)	1.894 (± 1.4058)		
PI, Triglycerides, Week 48, n=40, 45	1.309 (± 0.7647)	1.772 (± 1.1828)		
INI, Triglycerides, Baseline, n=82, 84	1.470 (± 1.0152)	1.426 (± 0.8720)		
INI, Triglycerides, Week 48, n=72, 77	1.405 (± 0.9068)	1.307 (± 0.7427)		
NNRTI, Triglycerides, Baseline, n=136, 140	1.322 (± 0.7986)	1.506 (± 1.4388)		
NNRTI, Triglycerides, Week 48, n=119, 120	1.305 (± 0.8771)	1.316 (± 0.7914)		
PI, Cholesterol, Baseline, n=46, 50	4.98 (± 0.960)	5.14 (± 1.152)		
PI, Cholesterol, Week 48, n=40, 45	5.07 (± 0.775)	5.16 (± 1.130)		
INI, Cholesterol, Baseline, n=82, 84	4.81 (± 1.077)	5.01 (± 1.080)		
INI, Cholesterol, Week 48, n=72, 77	4.90 (± 0.881)	4.87 (± 0.997)		
NNRTI, Cholesterol, Baseline, n=136, 140	4.87 (± 0.958)	4.98 (± 1.007)		
NNRTI, Cholesterol, Week 48, n=119, 120	4.93 (± 0.904)	4.91 (± 1.007)		
PI, HDL cholesterol, Baseline, n=46, 50	1.389 (± 0.4943)	1.537 (± 0.6096)		
PI, HDL cholesterol, Week 48, n=40, 45	1.505 (± 0.5459)	1.550 (± 0.5950)		
INI, HDL cholesterol, Baseline, n=82, 84	1.257 (± 0.3450)	1.383 (± 0.3890)		
INI, HDL cholesterol, Week 48, n=72, 77	1.288 (± 0.3664)	1.323 (± 0.3588)		
NNRTI, HDL cholesterol, Baseline, n=136, 140	1.449 (± 0.4756)	1.405 (± 0.4401)		
NNRTI, HDL cholesterol, Week 48, n=119, 120	1.442 (± 0.4413)	1.471 (± 0.4226)		
PI, LDL cholesterol, Baseline, n=43, 48	2.734 (± 0.7891)	2.743 (± 0.7948)		
PI, LDL cholesterol, Week 48, n=37, 43	2.944 (± 0.7175)	2.784 (± 0.8477)		
INI, LDL cholesterol, Basline, n=81, 83	2.881 (± 0.9196)	2.946 (± 0.8614)		
INI, LDL cholesterol, Week 48, n=71, 76	2.975 (± 0.8787)	2.939 (± 0.8591)		
NNRTI, LDL cholesterol, Baseline, n=134, 137	2.834 (± 0.8442)	2.901 (± 0.8714)		
NNRTI, LDL cholesterol, Week 48, n=116, 119	2.900 (± 0.8415)	2.834 (± 0.8763)		

Notes:

[109] - Safety Population

[110] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants discontinued or withdrawn due to AEs when

Baseline third agent treatment class was used over time including Week 48

End point title	Number of participants discontinued or withdrawn due to AEs when Baseline third agent treatment class was used over time including Week 48

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[111]	308[112]		
Units: Participants				
PI	2	2		
INI	6	0		
NNRTI	5	3		

Notes:

[111] - Safety Population

[112] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma trough concentration (Ctrough) for CAB LA evaluable

End point title	Plasma trough concentration (Ctrough) for CAB LA evaluable

End point description:

Blood samples will be collected at indicated time points for pharmacokinetic (PK) analysis of CAB LA. PK population includes all participants who received CAB and / or RPV and underwent PK sampling during the study, and provided CAB and /or RPV plasma concentration data. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Pre-dose at Weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA			
Subject group type	Subject analysis set			
Number of subjects analysed	308[113]			
Units: Micrograms per milliliter				
geometric mean (confidence interval 95%)				
Pre-dose, Week 8, n=252	1.2277 (1.1293 to 1.3346)			

Pre-dose, Week 12, n=261	1.6925 (1.6005 to 1.7897)			
Pre-dose, Week 16, n=248	1.9533 (1.8492 to 2.0632)			
Pre-dose, Week 20, n=233	2.1036 (1.9924 to 2.2209)			
Pre-dose, Week 24, n=234	2.2537 (2.1177 to 2.3984)			
Pre-dose, Week 28, n=232	2.4300 (2.3093 to 2.5569)			
Pre-dose, Week 32, n=219	2.4483 (2.3321 to 2.5703)			
Pre-dose, Week 36, n=209	2.4681 (2.3377 to 2.6057)			
Pre-dose, Week 40, n=209	2.5126 (2.3477 to 2.6890)			
Pre-dose, Week 44, n=221	2.7748 (2.6323 to 2.9250)			
Pre-dose, Week 48, n=217	2.8378 (2.6763 to 3.0090)			

Notes:

[113] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough for RPV LA evaluable

End point title	Ctrough for RPV LA evaluable

End point description:

Blood samples will be collected at indicated time points for PK analysis of RPV LA. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Pre-dose at Weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	RPV LA			
Subject group type	Subject analysis set			
Number of subjects analysed	308[114]			
Units: Nanograms per milliliter				
geometric mean (confidence interval 95%)				
Pre-dose, Week 8, n=251	38.58 (35.96 to 41.39)			

Pre-dose, Week 12, n=261	47.00 (44.50 to 49.64)			
Pre-dose, Week 16, n=247	53.87 (50.92 to 56.98)			
Pre-dose, Week 20, n=233	54.14 (51.13 to 57.34)			
Pre-dose, Week 24, n=231	61.26 (57.80 to 64.93)			
Pre-dose, Week 28, n=232	66.53 (62.87 to 70.40)			
Pre-dose, Week 32, n=218	70.93 (66.97 to 75.11)			
Pre-dose, Week 36, n=209	73.00 (68.54 to 77.75)			
Pre-dose, Week 40, n=208	76.24 (71.71 to 81.07)			
Pre-dose, Week 44, n=223	83.65 (78.94 to 88.63)			
Pre-dose, Week 48, n=216	90.28 (84.92 to 95.98)			

Notes:

[114] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the curve (AUC) for CAB LA and RPV LA evaluable

End point title	Area under the curve (AUC) for CAB LA and RPV LA evaluable

End point description:

Blood samples were collected at indicated time points to analyse AUC concentration in plasma for CAB LA. 99999 indicates data was not available due to sparse sampling post IM dosing.

End point type	Secondary

End point timeframe:

Pre-dose at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48; 1 Week post-dose at Weeks 5 and 41

End point values	CAB LA	RPV LA		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	308[115]	308[116]		
Units: Hours*microgram per milliliter				
geometric mean (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Notes:

[115] - PK Population

[116] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) in plasma for CAB LA evaluable at Week 41

End point title	Maximum concentration (Cmax) in plasma for CAB LA evaluable at Week 41

End point description:

Blood samples will be collected at indicated time points for PK analysis of CAB LA. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Week 41- 1 Week post dose

End point values	CAB LA			
Subject group type	Subject analysis set			
Number of subjects analysed	251[117]			
Units: Micrograms per milliliter				
geometric mean (confidence interval 95%)	3.3862 (3.1804 to 3.6054)			

Notes:

[117] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax in plasma for RPV LA evaluable at Week 41

End point title	Cmax in plasma for RPV LA evaluable at Week 41

End point description:

Blood samples will be collected at indicated time points for PK analysis of RPV LA. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Week 41- 1 Week post dose

End point values	RPV LA			
Subject group type	Subject analysis set			
Number of subjects analysed	251[118]			
Units: Nanograms per milliliter				
geometric mean (confidence interval 95%)	110.36 (103.28 to 117.93)			

Notes:

[118] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a virologic failure using snapshot algorithm by Baseline third agent

End point title	Percentage of participants with a virologic failure using snapshot algorithm by Baseline third agent

End point description:

Percentage of participants with virologic failure endpoint as per FDA snapshot algorithm at Week 48 was assessed based on the non-inferior antiviral activity of switching IM CAB LA+RPV LA every 4 weeks compared to continuation of current ART regimen over 48 weeks in HIV-1 infected ART-experienced participants. The HIV-RNA >=50 copies/mL per snapshot algorithm was determined using a Cochran-Mantel Haenszel test stratified by baseline third agent class: INI, NNRTI, or PI. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[119]	308[120]		
Units: Percentage of participants				
number (not applicable)				
PI, n=51, 54	2.0	0		
INI, n=102, 99	0	2.0		
NNRTI, n=155, 155	2.6	0.6		

Notes:

[119] - ITT-E Population.

[120] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <50copies/mL using snapshot algorithm by Baseline third agent

End point title	Percentage of participants with plasma HIV-1 RNA <50copies/mL using snapshot algorithm by Baseline third agent

End point description:

Percentage of participants with HIV-1 RNA < 50copies/mL endpoint as per FDA snapshot algorithm at Week 48 was assessed based on the non-inferior antiviral activity of switching IM CAB LA+RPV LA every 4 weeks compared to continuation of current ART regimen over 48 weeks in HIV-1 infected ART-experienced participants. The HIV-RNA <50 copies/mL per snapshot algorithm was determined using a Cochran-Mantel Haenszel test stratified by baseline third agent class: INI, NNRTI, or PI. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[121]	308[122]		
Units: Percentage of participants				
number (not applicable)				
PI, n=51, 54	92	94		
INI, n=102, 99	94	96		
NNRTI, n=155, 155	92	95		

Notes:

[121] - ITT-E Population

[122] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with severity of adverse events by Baseline third agents

End point title	Number of participants with severity of adverse events by Baseline third agents

End point description:

Severity of AEs were defined as per The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table). Severity grades for AEs were: Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (Potentially life-threatening) and Grade 5 were all deaths related to an AE.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[123]	308[124]		
Units: Participants				
PI, Grade 1	22	20		
PI, Grade 2	20	11		
PI, Grade 3	4	4		
PI, Grade 4	1	0		
PI, Grade 5	0	1		
INI, Grade 1	40	40		
INI, Grade 2	50	23		
INI, Grade 3	8	3		
INI, Grade 4	1	2		
INI, Grade 5	0	0		
NNRTI, Grade 1	39	55		
NNRTI, Grade 2	88	47		
NNRTI, Grade 3	15	12		
NNRTI, Grade 4	6	2		
NNRTI, Grade 5	0	0		

Notes:

[123] - Safety Population

[124] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: ALT, ALP, AST and CK

End point title	Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: ALT, ALP, AST and CK

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: ALT, ALP, AST and CK to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[125]	308[126]		
Units: International units per liter				
arithmetic mean (standard deviation)				
PI, ALT, Week 4, n=51, 53	9.4 (± 17.93)	1.1 (± 9.99)		
PI, ALT, Week 8, n=34, 53	7.9 (± 17.19)	0.9 (± 7.20)		
PI, ALT, Week 12, n=50, 52	5.3 (± 17.31)	1.4 (± 9.76)		
PI, ALT, Week 16, n=48, 53	6.5 (± 20.92)	1.4 (± 8.75)		
PI, ALT, Week 20, n=46, 53	4.9 (± 18.06)	0.3 (± 7.34)		
PI, ALT, Week 24, n=47, 53	4.1 (± 14.42)	0.5 (± 7.30)		
PI, ALT, Week 28, n=42, 53	2.6 (± 11.47)	0.8 (± 7.46)		
PI, ALT, Week 32, n=45, 51	3.5 (± 14.88)	0.5 (± 7.36)		
PI, ALT, Week 36, n=44, 50	3.3 (± 13.55)	2.0 (± 9.78)		
PI, ALT, Week 40, n=42, 51	5.4 (± 17.81)	1.1 (± 10.52)		
PI, ALT, Week 44, n=47, 51	4.0 (± 15.83)	0.9 (± 11.97)		
PI, ALT, Week 48, n=43, 50	2.9 (± 10.69)	0.5 (± 8.04)		
INI, ALT, Week 4, n=99, 97	1.7 (± 15.15)	0.7 (± 7.20)		
INI, ALT, Week 8, n=73, 98	3.3 (± 18.20)	5.4 (± 50.20)		
INI, ALT, Week 12, n=99, 95	-1.0 (± 12.48)	1.7 (± 10.63)		
INI, ALT, Week 16, n=93, 96	-1.8 (± 12.27)	-0.1 (± 8.58)		
INI, ALT, Week 20, n=93, 97	-1.9 (± 13.60)	-0.5 (± 9.38)		
INI, ALT, Week 24, n=94, 95	0.6 (± 17.33)	0.1 (± 9.95)		
INI, ALT, Week 28, n=89, 93	-2.4 (± 9.70)	-0.4 (± 12.31)		

INI, ALT, Week 32, n=93, 95	-1.8 (± 12.87)	-0.3 (± 7.79)		
INI, ALT, Week 36, n=94, 95	1.5 (± 35.82)	-0.4 (± 8.79)		
INI, ALT, Week 40, n=90, 95	5.0 (± 59.10)	-0.6 (± 9.62)		
INI, ALT, Week 44, n=91, 94	-1.6 (± 13.90)	-0.4 (± 7.91)		
INI, ALT, Week 48, n=91, 95	-0.2 (± 15.17)	-0.8 (± 7.41)		
NNRTI, ALT, Week 4, n=151, 153	-2.6 (± 9.82)	-0.7 (± 10.80)		
NNRTI, ALT, Week 8, n=122, 152	-2.9 (± 11.62)	-0.8 (± 12.06)		
NNRTI, ALT, Week 12, n=146, 152	9.5 (± 160.61)	-0.8 (± 12.66)		
NNRTI, ALT, Week 16, n=143, 149	-1.3 (± 26.21)	-1.6 (± 11.39)		
NNRTI, ALT, Week 20, n=138, 152	-2.0 (± 28.04)	-2.0 (± 12.61)		
NNRTI, ALT, Week 24, n=143, 151	2.6 (± 85.48)	-1.3 (± 11.85)		
NNRTI, ALT, Week 28, n=136, 150	-4.5 (± 11.46)	-0.5 (± 14.03)		
NNRTI, ALT, Week 32, n=137, 148	-3.8 (± 14.93)	-0.9 (± 14.33)		
NNRTI, ALT, Week 36, n=135, 147	-3.8 (± 12.44)	-0.1 (± 12.48)		
NNRTI, ALT, Week 40, n=138, 147	-3.8 (± 13.48)	-0.4 (± 13.47)		
NNRTI, ALT, Week 44, n=137, 148	-4.7 (± 12.67)	-0.4 (± 14.67)		
NNRTI, ALT, Week 48, n=131, 147	-4.6 (± 12.38)	-0.9 (± 12.75)		
PI, ALP, Week 4, n=51, 53	-3.5 (± 11.63)	-2.9 (± 8.07)		
PI, ALP, Week 8, n=34, 53	-2.1 (± 24.59)	0.2 (± 11.37)		
PI, ALP, Week 12, n=50, 52	-5.7 (± 14.40)	0.9 (± 10.22)		
PI, ALP, Week 16, n=48, 53	-7.3 (± 17.09)	0.6 (± 8.68)		
PI, ALP, Week 20, n=46, 53	-6.8 (± 16.71)	0.1 (± 10.70)		
PI, ALP, Week 24, n=47, 53	-7.5 (± 17.90)	-0.4 (± 7.67)		
PI, ALP, Week 28, n=42, 53	-7.3 (± 17.23)	3.0 (± 9.69)		
PI, ALP, Week 32, n=45, 51	-9.3 (± 16.47)	-0.7 (± 8.50)		
PI, ALP, Week 36, n=44, 50	-10.2 (± 18.52)	0.6 (± 13.52)		
PI, ALP, Week 40, n=42, 51	-8.7 (± 17.37)	-1.4 (± 8.79)		
PI, ALP, Week 44, n=47, 51	-11.5 (± 17.49)	-0.9 (± 9.05)		
PI, ALP, Week 48, n=43, 50	-8.0 (± 16.05)	-0.2 (± 9.08)		
INI, ALP, Week 4, n=99, 97	-0.5 (± 10.59)	-0.9 (± 7.92)		
INI, ALP, Week 8, n=73, 98	-1.8 (± 8.55)	4.9 (± 33.17)		
INI, ALP, Week 12, n=99, 95	-1.6 (± 8.57)	3.5 (± 19.97)		
INI, ALP, Week 16, n=93, 96	-1.7 (± 10.53)	-0.2 (± 10.93)		
INI, ALP, Week 20, n=93, 97	-2.0 (± 10.23)	-0.4 (± 7.93)		
INI, ALP, Week 24, n=94, 95	-1.4 (± 10.23)	-0.6 (± 8.25)		
INI, ALP, Week 28, n=89, 93	-2.1 (± 10.83)	-0.8 (± 8.80)		
INI, ALP, Week 32, n=93, 95	-1.6 (± 11.08)	-2.0 (± 8.23)		
INI, ALP, Week 36, n=94, 95	-2.4 (± 12.03)	-2.2 (± 9.41)		
INI, ALP, Week 40, n=90, 95	-0.9 (± 13.77)	-1.9 (± 9.33)		
INI, ALP, Week 44, n=91, 94	-2.6 (± 13.69)	-0.4 (± 11.60)		
INI, ALP, Week 48, n=91, 95	-1.9 (± 13.29)	-1.2 (± 10.26)		
NNRTI, ALP, Week 4, n=151, 153	-10.4 (± 12.81)	-2.7 (± 9.60)		
NNRTI, ALP, Week 8, n=122, 152	-10.9 (± 16.50)	-1.0 (± 10.77)		
NNRTI, ALP, Week 12, n=146, 152	-13.0 (± 26.62)	-0.7 (± 11.04)		
NNRTI, ALP, Week 16, n=143, 149	-15.7 (± 22.52)	-1.0 (± 10.54)		
NNRTI, ALP, Week 20, n=138, 152	-14.9 (± 22.35)	-1.8 (± 13.77)		

NNRTI, ALP, Week 24, n=143, 151	-14.5 (± 21.88)	0.4 (± 12.75)		
NNRTI, ALP, Week 28, n=136, 150	-16.2 (± 21.66)	-1.0 (± 13.18)		
NNRTI, ALP, Week 32, n=137, 148	-15.8 (± 21.98)	-1.8 (± 13.63)		
NNRTI, ALP, Week 36, n=135, 147	-16.1 (± 23.60)	-1.0 (± 11.86)		
NNRTI, ALP, Week 40, n=138, 147	-17.2 (± 22.83)	-0.4 (± 13.19)		
NNRTI, ALP, Week 44, n=137, 148	-17.3 (± 23.32)	-0.8 (± 13.20)		
NNRTI, ALP, Week 48, n=131, 147	-18.0 (± 27.97)	0.2 (± 14.69)		
PI, AST, Week 4, n=51, 53	3.8 (± 9.18)	2.3 (± 16.78)		
PI, AST, Week 8, n=34, 53	5.1 (± 8.35)	-0.1 (± 4.60)		
PI, AST, Week 12, n=50, 52	2.7 (± 11.49)	1.7 (± 7.21)		
PI, AST, Week 16, n=48, 53	3.9 (± 16.81)	1.8 (± 10.69)		
PI, AST, Week 20, n=46, 53	4.1 (± 20.85)	0.5 (± 4.29)		
PI, AST, Week 24, n=47, 53	1.5 (± 7.76)	1.6 (± 9.93)		
PI, AST, Week 28, n=42, 53	2.9 (± 8.86)	1.9 (± 7.45)		
PI, AST, Week 32, n=45, 51	3.1 (± 14.13)	0.6 (± 4.93)		
PI, AST, Week 36, n=44, 50	1.7 (± 8.04)	1.9 (± 6.24)		
PI, AST, Week 40, n=42, 51	5.7 (± 24.61)	0.5 (± 6.05)		
PI, AST, Week 44, n=47, 51	1.7 (± 9.71)	1.4 (± 11.60)		
PI, AST, Week 48, n=43, 50	1.7 (± 7.09)	2.1 (± 8.74)		
INI, AST, Week 4, n=99, 97	0.0 (± 15.36)	-0.1 (± 6.29)		
INI, AST, Week 8, n=73, 98	3.3 (± 25.01)	1.2 (± 21.48)		
INI, AST, Week 12, n=99, 95	-1.3 (± 14.22)	0.8 (± 7.35)		
INI, AST, Week 16, n=93, 96	-2.1 (± 12.73)	0.1 (± 10.96)		
INI, AST, Week 20, n=93, 97	-1.7 (± 13.77)	-0.9 (± 12.67)		
INI, AST, Week 24, n=94, 95	-0.4 (± 14.88)	-0.2 (± 10.40)		
INI, AST, Week 28, n=89, 93	-1.4 (± 7.74)	-0.9 (± 13.48)		
INI, AST, Week 32, n=93, 95	-2.1 (± 13.06)	-0.8 (± 10.01)		
INI, AST, Week 36, n=94, 95	-0.7 (± 17.34)	-1.1 (± 11.70)		
INI, AST, Week 40, n=90, 95	1.0 (± 20.11)	-0.4 (± 13.96)		
INI, AST, Week 44, n=91, 94	1.0 (± 24.54)	-0.7 (± 10.69)		
INI, AST, Week 48, n=91, 95	0.4 (± 16.57)	0.2 (± 11.91)		
NNRTI, AST, Week 4, n=151, 153	-1.9 (± 11.09)	-0.5 (± 8.73)		
NNRTI, AST, Week 8, n=122, 152	-1.3 (± 18.14)	-0.9 (± 8.31)		
NNRTI, AST, Week 12, n=146, 152	4.7 (± 91.54)	0.0 (± 10.08)		
NNRTI, AST, Week 16, n=143, 149	0.3 (± 21.80)	-1.0 (± 8.37)		
NNRTI, AST, Week 20, n=138, 152	-1.2 (± 17.47)	-0.7 (± 9.09)		
NNRTI, AST, Week 24, n=143, 150	-0.1 (± 31.53)	-0.4 (± 8.87)		
NNRTI, AST, Week 28, n=136, 150	-2.8 (± 9.02)	0.4 (± 10.70)		
NNRTI, AST, Week 32, n=137, 148	-2.0 (± 18.27)	1.5 (± 16.84)		
NNRTI, AST, Week 36, n=135, 147	-2.5 (± 10.33)	0.2 (± 9.00)		
NNRTI, AST, Week 40, n=138, 147	-2.7 (± 11.14)	0.1 (± 9.40)		
NNRTI, AST, Week 44, n=137, 148	-3.4 (± 10.38)	0.1 (± 11.20)		
NNRTI, AST, Week 48, n=131, 147	-2.9 (± 10.87)	0.5 (± 10.60)		
PI, CK, Week 4, n=51, 53	8.6 (± 182.21)	133.5 (± 907.82)		
PI, CK, Week 8, n=34, 53	67.9 (± 176.14)	23.5 (± 174.40)		

PI, CK, Week 12, n=50, 52	3.1 (± 162.71)	57.9 (± 406.52)		
PI, CK, Week 16, n=48, 53	19.4 (± 253.86)	16.3 (± 66.34)		
PI, CK, Week 20, n=46, 53	103.6 (± 696.54)	6.8 (± 72.86)		
PI, CK, Week 24, n=47, 53	-3.0 (± 181.03)	18.2 (± 86.69)		
PI, CK, Week 28, n=42, 53	60.3 (± 299.83)	13.5 (± 93.14)		
PI, CK, Week 32, n=45, 51	157.1 (± 988.65)	1.5 (± 64.94)		
PI, CK, Week 36, n=44, 50	-9.0 (± 191.25)	22.3 (± 62.09)		
PI, CK, Week 40, n=42, 51	193.7 (± 1188.89)	0.3 (± 48.24)		
PI, CK, Week 44, n=47, 51	-6.3 (± 185.69)	4.8 (± 62.91)		
PI, CK, Week 48, n=43, 50	-1.0 (± 158.33)	72.9 (± 478.94)		
INI, CK, Week 4, n=99, 97	-32.7 (± 717.86)	-17.9 (± 260.84)		
INI, CK, Week 8, n=73, 98	95.6 (± 801.75)	-58.0 (± 577.11)		
INI, CK, Week 12, n=99, 95	-16.1 (± 852.44)	-23.9 (± 304.61)		
INI, CK, Week 16, n=93, 96	-59.5 (± 629.54)	-1.9 (± 686.38)		
INI, CK, Week 20, n=93, 97	-55.7 (± 623.92)	-58.1 (± 622.84)		
INI, CK, Week 24, n=94, 95	-63.1 (± 549.02)	-40.7 (± 588.24)		
INI, CK Week 28, n=89, 93	-17.4 (± 224.35)	-27.4 (± 759.07)		
INI, CK, Week 32, n=93, 95	-82.8 (± 587.51)	-42.1 (± 637.00)		
INI, CK, Week 36, n=94, 95	-76.1 (± 602.03)	-60.9 (± 603.48)		
INI, CK, Week 40, n=90, 95	40.3 (± 864.00)	-36.2 (± 609.80)		
INI, CK, Week 44, n=91, 94	199.8 (± 2043.35)	-60.2 (± 576.84)		
INI, CK, Week 48, n=91, 95	20.5 (± 861.55)	-25.0 (± 653.03)		
NNRTI, CK, Week 4, n=151, 153	18.2 (± 502.12)	26.0 (± 214.58)		
NNRTI, CK, Week 8, n=122, 152	108.2 (± 1339.52)	-3.6 (± 108.28)		
NNRTI, CK, Week 12, n=146, 152	21.9 (± 440.81)	24.5 (± 222.26)		
NNRTI, CK, Week 16, n=143, 149	139.9 (± 1121.08)	7.0 (± 189.21)		
NNRTI, CK, Week 20, n=138, 152	65.5 (± 656.11)	1.6 (± 114.05)		
NNRTI, CK, Week 24, n=143, 151	24.1 (± 606.47)	17.7 (± 167.38)		
NNRTI, CK, Week 28, n=136, 150	-10.9 (± 169.29)	53.2 (± 462.07)		
NNRTI, CK, Week 32, n=137, 148	31.3 (± 650.27)	94.0 (± 665.17)		
NNRTI, CK, Week 36, n=135, 147	19.0 (± 440.56)	10.3 (± 135.08)		

NNRTI, CK, Week 40, n=138, 147	-7.7 (± 237.00)	22.6 (± 195.23)		
NNRTI, CK, Week 44, n=137, 148	-35.4 (± 183.15)	14.9 (± 173.39)		
NNRTI, CK, Week 48, n=131, 147	-15.1 (± 212.52)	27.3 (± 272.59)		

Notes:

[125] - Safety Population

[126] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Albumin

End point title	Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Albumin

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: albumin to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[127]	308[128]		
Units: Grams per Liter				
arithmetic mean (standard deviation)				
PI, Week 4, n=51, 53	0.2 (± 2.21)	-0.2 (± 2.41)		
PI, Week 8, n=34, 53	0.7 (± 2.73)	-0.1 (± 2.74)		
PI, Week 12, n=50, 52	-0.2 (± 2.67)	-0.3 (± 2.81)		
PI, Week 16, n=48, 53	-0.2 (± 2.77)	-0.8 (± 2.72)		
PI, Week 20, n=46, 53	-0.4 (± 2.35)	-0.8 (± 2.82)		
PI, Week 24, n=47, 53	-0.6 (± 2.24)	-0.8 (± 2.40)		
PI, Week 28, n=42, 53	-0.6 (± 2.26)	-1.4 (± 2.08)		
PI, Week 32, n=45, 51	-0.7 (± 2.39)	-0.5 (± 2.42)		
PI, Week 36, n=44, 50	-0.6 (± 2.44)	-0.9 (± 2.48)		
PI, Week 40, n=42, 51	-0.1 (± 2.72)	-0.5 (± 2.37)		
PI, Week 44, n=47, 51	-0.5 (± 2.15)	-0.5 (± 2.60)		
PI, Week 48, n=43, 50	-0.3 (± 2.74)	-0.1 (± 2.44)		
INI, Week 4, n=99, 97	-0.4 (± 2.56)	-0.9 (± 2.62)		
INI, Week 8, n=73, 98	-0.5 (± 2.59)	-1.0 (± 2.89)		
INI, Week 12, n=99, 95	-0.3 (± 2.92)	-0.5 (± 2.59)		
INI, Week 16, n=93, 96	-0.5 (± 2.78)	-1.1 (± 2.80)		
INI, Week 20, n=93, 97	-0.7 (± 2.71)	-0.7 (± 2.77)		

INI, Week 24, n=94, 95	-0.8 (± 2.86)	-1.0 (± 2.74)		
INI, Week 28, n=89, 93	-0.3 (± 2.55)	-1.1 (± 2.87)		
INI, Week 32, n=93, 95	-0.2 (± 2.70)	-1.3 (± 2.77)		
INI, Week 36, n=94, 95	-0.8 (± 2.67)	-1.1 (± 2.54)		
INI, Week 40, n=90, 95	-0.3 (± 2.40)	-1.3 (± 2.84)		
INI, Week 44, n=91, 94	-0.5 (± 2.77)	-1.0 (± 2.76)		
INI, Week 48, n=91, 95	-0.1 (± 2.69)	-0.5 (± 2.69)		
NNRTI, Week 4, n=151, 153	-0.8 (± 2.70)	-0.3 (± 2.42)		
NNRTI, Week 8, n=122, 152	-0.4 (± 2.83)	-0.6 (± 2.53)		
NNRTI, Week 12, n=146, 152	-0.8 (± 2.59)	-0.3 (± 2.61)		
NNRTI, Week 16, n=143, 149	-0.8 (± 2.79)	-0.7 (± 2.63)		
NNRTI, Week 20, n=138, 152	-0.9 (± 2.96)	-0.9 (± 2.33)		
NNRTI, Week 24, n=143, 151	-0.7 (± 2.73)	-0.7 (± 2.57)		
NNRTI, Week 28, n=136, 150	-0.9 (± 2.72)	-0.9 (± 2.34)		
NNRTI, Week 32, n=137, 148	-0.9 (± 2.94)	-1.0 (± 2.45)		
NNRTI, Week 36, n=135, 147	-1.0 (± 2.83)	-0.8 (± 2.79)		
NNRTI, Week 40, n=138, 147	-0.7 (± 2.54)	-1.0 (± 2.52)		
NNRTI, Week 44, n=137, 148	-0.3 (± 2.60)	-0.8 (± 2.22)		
NNRTI, Week 48, n=131, 147	-0.6 (± 2.57)	-0.5 (± 2.49)		

Notes:

[127] - Safety Population

[128] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Bilirubin, direct bilirubin and creatinine

End point title	Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Bilirubin, direct bilirubin and creatinine

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: bilirubin, direct bilirubin and creatinine to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[129]	308[130]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
PI, Bilirubin, Week 4, n=51, 53	-9.0 (± 20.62)	0.3 (± 6.95)		
PI, Bilirubin, Week 8, n=34, 53	-6.6 (± 13.76)	0.1 (± 5.76)		

PI, Bilirubin, Week 12, n=50, 52	-10.2 (± 20.18)	1.7 (± 7.11)		
PI, Bilirubin, Week 16, n=48, 53	-10.0 (± 20.13)	0.6 (± 6.42)		
PI, Bilirubin, Week 20, n=46, 53	-9.2 (± 20.21)	1.5 (± 12.45)		
PI, Bilirubin, Week 24, n=47, 53	-9.6 (± 20.64)	2.7 (± 11.87)		
PI, Bilirubin, Week 28, n=42, 53	-10.0 (± 22.42)	0.9 (± 7.70)		
PI, Bilirubin, Week 32, n=45, 51	-8.9 (± 21.34)	2.7 (± 8.64)		
PI, Bilirubin, Week 36, n=44, 50	-10.5 (± 21.75)	2.6 (± 7.35)		
PI, Bilirubin, Week 40, n=42, 51	-11.0 (± 22.20)	3.5 (± 12.74)		
PI, Bilirubin, Week 44, n=47, 51	-9.6 (± 20.32)	3.7 (± 9.10)		
PI, Bilirubin, Week 48, n=43, 50	-10.7 (± 21.77)	2.3 (± 5.23)		
INI, Bilirubin, Week 4, n=99, 97	0.2 (± 3.92)	-0.7 (± 3.93)		
INI, Bilirubin, Week 8, n=73, 98	0.4 (± 3.96)	0.9 (± 12.43)		
INI, Bilirubin, Week 12, n=99, 95	0.6 (± 4.41)	-0.5 (± 4.69)		
INI, Bilirubin, Week 16, n=93, 96	0.6 (± 4.30)	-0.2 (± 4.35)		
INI, Bilirubin, Week 20, n=93, 97	0.9 (± 4.08)	-0.5 (± 4.32)		
INI, Bilirubin, Week 24, n=94, 94	0.2 (± 3.72)	-0.5 (± 3.88)		
INI, Bilirubin, Week 28, n=89, 93	1.1 (± 3.58)	-0.4 (± 4.85)		
INI, Bilirubin, Week 32, n=93, 95	0.7 (± 4.67)	-1.1 (± 4.54)		
INI, Bilirubin, Week 36, n=94, 95	0.5 (± 4.07)	-0.6 (± 4.62)		
INI, Bilirubin, Week 40, n=90, 95	0.6 (± 4.28)	-1.0 (± 4.26)		
INI, Bilirubin, Week 44, n=91, 94	0.9 (± 4.34)	-0.7 (± 4.72)		
INI, Bilirubin, Week 48, n=91, 95	1.1 (± 3.72)	-0.9 (± 3.96)		
NNRTI, Bilirubin, Week 4, n=151, 153	1.4 (± 3.87)	-0.4 (± 2.85)		
NNRTI, Bilirubin, Week 8, n=122, 152	1.4 (± 3.84)	-0.4 (± 2.43)		
NNRTI, Bilirubin, Week 12, n=146, 152	2.0 (± 4.69)	-0.2 (± 3.01)		
NNRTI, Bilirubin, Week 16, n=143, 149	3.3 (± 14.12)	-0.5 (± 2.66)		
NNRTI, Bilirubin, Week 20, n=138, 152	2.1 (± 4.90)	-0.1 (± 2.81)		
NNRTI, Bilirubin, Week 24, n=143, 151	1.8 (± 3.91)	-0.3 (± 2.84)		
NNRTI, Bilirubin, Week 28, n=136, 150	2.4 (± 4.11)	-0.4 (± 3.04)		
NNRTI, Bilirubin, Week 32, n=137, 148	2.2 (± 4.76)	-0.3 (± 2.57)		
NNRTI, Bilirubin, Week 36, n=135, 147	1.8 (± 4.14)	-0.2 (± 2.61)		
NNRTI, Bilirubin, Week 40, n=138, 147	2.2 (± 4.43)	-0.2 (± 2.61)		
NNRTI, Bilirubin, Week 44, n=137, 148	2.0 (± 4.15)	-0.1 (± 2.72)		
NNRTI, Bilirubin, Week 48, n=131, 147	2.2 (± 4.59)	0.1 (± 2.98)		
PI, Direct bilirubin, Week 4, n=51, 53	-1.2 (± 2.34)	0.3 (± 1.40)		
PI, Direct bilirubin, Week 8, n=34, 53	-0.9 (± 2.16)	-0.1 (± 1.44)		
PI, Direct bilirubin, Week 12, n=50, 52	-1.6 (± 2.16)	0.3 (± 1.39)		
PI, direct bilirubin, Week 16, n=48, 53	-1.7 (± 2.12)	0.0 (± 1.30)		
PI, Direct bilirubin, Week 20, n=46, 53	-1.5 (± 2.27)	0.0 (± 1.86)		
PI, Direct bilirubin, Week 24, n=47, 53	-1.4 (± 2.27)	0.2 (± 1.72)		
PI, Direct bilirubin, Week 28, n=42, 53	-1.6 (± 2.43)	-0.3 (± 1.52)		
PI, Direct bilirubin, Week 32, n=45, 51	-1.4 (± 2.48)	0.2 (± 1.74)		
PI, Direct bilirubin, Week 36, n=44, 50	-1.8 (± 2.29)	0.2 (± 1.49)		
PI, Direct bilirubin, Week 40, n=42, 51	-1.8 (± 2.29)	0.2 (± 1.43)		
PI, Direct bilirubin, Week 44, n=47, 51	-1.5 (± 2.22)	0.3 (± 1.52)		
PI, Direct bilirubin, Week 48, n=43, 50	-1.5 (± 2.35)	0.2 (± 1.36)		
INI, Direct bilirubin, Week 4, n=99, 97	0.0 (± 1.11)	0.0 (± 1.19)		
INI, Direct bilirubin, Week 8, n=73, 98	0.0 (± 1.13)	0.7 (± 6.76)		

INI, Direct bilirubin, Week 12, n=99, 95	0.0 (± 1.14)	0.0 (± 1.29)		
INI, Direct bilirubin, Week 16, n=93, 96	0.0 (± 1.14)	-0.3 (± 1.06)		
INI, Direct bilirubin, Week 20, n=93, 97	-0.2 (± 0.96)	-0.2 (± 1.23)		
INI, Direct bilirubin, Week 24, n=94, 94	-0.1 (± 1.07)	-0.3 (± 1.16)		
INI, Direct bilirubin, Week 28, n=89, 93	-0.1 (± 0.97)	-0.2 (± 1.30)		
INI, Direct bilirubin, Week 32, n=93, 95	-0.2 (± 1.24)	-0.4 (± 1.15)		
INI, Direct bilirubin, Week 36, n=94, 95	-0.2 (± 1.33)	-0.3 (± 1.18)		
INI, Direct bilirubin, Week 40, n=90, 95	-0.1 (± 1.10)	-0.4 (± 1.24)		
INI, Direct bilirubin. Week 44, n=91, 94	0.0 (± 1.14)	-0.3 (± 1.11)		
INI, Direct bilirubin, Week 48, n=91, 95	0.0 (± 1.01)	-0.1 (± 1.28)		
NNRTI, Direct bilirubin, Week 4, n=151, 153	0.1 (± 1.14)	0.1 (± 1.12)		
NNRTI, Direct bilirubin, Week 8, n=122, 152	0.1 (± 1.24)	0.0 (± 1.03)		
NNRTI, Direct bilirubin, Week 12, n=146, 152	0.2 (± 1.38)	0.0 (± 1.08)		
NNRTI, Direct bilirubin, Week 16, n=143, 149	0.7 (± 6.82)	-0.1 (± 1.09)		
NNRTI, Direct bilirubin, Week 20, n=138, 152	0.1 (± 1.32)	-0.2 (± 1.08)		
NNRTI, Direct bilirubin, Week 24, n=143, 151	0.1 (± 1.34)	-0.1 (± 1.06)		
NNRTI, Direct bilirubin, Week 28, n=136, 150	0.1 (± 1.29)	-0.2 (± 1.19)		
NNRTI, Direct bilirubin, Week 32, n=137, 148	0.0 (± 1.31)	-0.2 (± 1.06)		
NNRTI, Direct bilirubin, Week 36, n=135, 147	0.0 (± 1.47)	-0.2 (± 1.09)		
NNRTI, Direct bilirubin, Week 40, n=138, 147	0.0 (± 1.55)	-0.2 (± 1.01)		
NNRTI, Direct bilirubin, Week 44, n=137, 148	0.1 (± 1.28)	-0.1 (± 1.08)		
NNRTI, Direct bilirubin, Week 48, n=131, 147	0.1 (± 1.27)	0.0 (± 1.16)		
PI, Creatinine, Week 4, n=51, 53	1.46 (± 7.726)	2.16 (± 6.737)		
PI, Creatinine, Week 8, n=34, 53	0.87 (± 7.777)	1.17 (± 5.605)		
PI, Creatinine, Week 12, n=50, 52	-1.66 (± 8.971)	3.01 (± 5.406)		
PI, Creatinine, Week 16, n=48, 53	-0.90 (± 8.658)	2.88 (± 5.918)		
PI, Creatinine, Week 20, n=46, 53	1.63 (± 8.709)	5.00 (± 9.336)		
PI, Creatinine, Week 24, n=47, 53	0.48 (± 7.143)	2.47 (± 6.821)		
PI, Creatinine, Week 28, n=42, 53	3.06 (± 9.741)	3.05 (± 6.908)		
PI, Creatinine, Week 32, n=45, 51	2.29 (± 10.124)	3.79 (± 6.540)		
PI, Creatinine, Week 36, n=44, 50	2.20 (± 7.347)	2.36 (± 6.291)		
PI, Creatinine, Week 40, n=42, 51	1.10 (± 9.155)	3.46 (± 6.166)		
PI, Creatinine, Week 44, n=47, 51	3.01 (± 8.981)	2.73 (± 6.169)		
PI, Creatinine, Week 48, n=43, 50	4.41 (± 10.009)	1.86 (± 5.575)		
INI, Creatinine, Week 4, n=99, 95	-1.61 (± 8.848)	1.64 (± 10.592)		
INI, Creatinine, Week 8, n=73, 98	-3.93 (± 10.030)	1.56 (± 9.444)		
INI, Creatinine, Week 12, n=99, 95	-2.47 (± 10.973)	3.03 (± 10.203)		
INI, Creatinine, Week 16, n=93, 96	-3.93 (± 9.000)	0.36 (± 8.651)		

INI, Creatinine, Week 20, n=93, 97	-3.73 (± 9.101)	0.86 (± 9.608)		
INI, Creatinine, Week 24, n=94, 94	-4.25 (± 8.281)	0.87 (± 10.493)		
INI, Creatinine, Week 28, n=89, 93	-3.54 (± 10.713)	0.92 (± 10.086)		
INI, Creatinine, Week 32, n=93, 95	-3.48 (± 10.591)	0.86 (± 9.754)		
INI, Creatinine, Week 36, n=94, 95	-4.31 (± 10.360)	1.34 (± 9.369)		
INI, Creatinine, Week 40, n=90, 95	-3.08 (± 9.913)	1.66 (± 10.272)		
INI, Creatinine, Week 44, n=91, 94	-3.33 (± 9.165)	0.98 (± 10.443)		
INI, Creatinine, Week 48, n=91, 95	-2.99 (± 9.442)	0.47 (± 9.602)		
NNRTI, Creatinine, Week 4, n=151, 153	2.86 (± 7.456)	1.77 (± 6.484)		
NNRTI, Creatinine, Week 8, n=122, 152	0.86 (± 8.263)	1.05 (± 6.790)		
NNRTI, Creatinine, Week 12, n=146, 152	1.47 (± 7.928)	0.44 (± 6.096)		
NNRTI, Creatinine, Week 16, n=143, 149	1.67 (± 8.934)	1.98 (± 8.475)		
NNRTI, Creatinine, Week 20, n=138, 152	3.04 (± 8.836)	1.27 (± 7.023)		
NNRTI, Creatinine, Week 24, n=143, 151	4.42 (± 14.819)	1.28 (± 6.553)		
NNRTI, Creatinine, Week 28, n=136, 150	3.61 (± 10.627)	1.50 (± 7.483)		
NNRTI, Creatinine, Week 32, n=137, 148	2.26 (± 9.033)	2.01 (± 7.811)		
NNRTI, Creatinine, Week 36, n=135, 147	2.98 (± 10.596)	1.54 (± 7.354)		
NNRTI, Creatinine, Week 40, n=138, 147	3.39 (± 9.496)	0.99 (± 7.471)		
NNRTI, Creatinine, Week 44, n=137, 148	3.24 (± 8.892)	1.21 (± 6.686)		
NNRTI, Creatinine, Week 48, n=131, 147	3.84 (± 11.860)	0.69 (± 7.241)		

Notes:

[129] - Safety Population

[130] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Creatinine clearance

End point title	Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Creatinine clearance

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: creatinine clearance to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). GFR will be estimated by the central laboratory using the CKD-EPI. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[131]	308[132]		
Units: Milliliters per minute per 1.73meter^2				
arithmetic mean (standard deviation)				
PI, Week 4, n=51, 53	-2.2 (± 9.77)	-2.8 (± 8.02)		
PI, Week 8, n=34, 53	-1.1 (± 10.19)	-1.3 (± 6.58)		
PI, Week 12, n=50, 52	2.2 (± 11.04)	-3.7 (± 6.99)		
PI, Week 16, n=48, 53	0.9 (± 11.02)	-3.1 (± 7.63)		
PI, Week 20, n=46, 53	-2.2 (± 10.80)	-5.0 (± 9.26)		
PI, Week 24, n=47, 53	-1.0 (± 8.60)	-3.8 (± 8.51)		
PI, Week 28, n=42, 53	-4.2 (± 11.82)	-4.0 (± 8.46)		
PI, Week 32, n=45, 51	-3.2 (± 12.30)	-5.2 (± 7.56)		
PI, Week 36, n=44, 50	-3.8 (± 8.68)	-3.6 (± 8.08)		
PI, Week 40, n=42, 51	-2.4 (± 10.71)	-4.9 (± 7.25)		
PI, Week 44, n=47, 51	-4.5 (± 10.63)	-4.2 (± 7.58)		
PI, Week 48, n=43, 50	-5.6 (± 12.22)	-3.1 (± 6.54)		
INI, Week 4, n=99, 95	1.0 (± 9.51)	-2.0 (± 11.28)		
INI, Week 8, n=72, 98	3.9 (± 9.84)	-1.9 (± 9.28)		
INI, Week 12, n=99, 93	2.1 (± 11.32)	-3.1 (± 9.60)		
INI, Week 16, n=93, 96	3.6 (± 9.71)	-0.7 (± 8.59)		
INI, Week 20, n=93, 97	3.5 (± 9.77)	-1.7 (± 9.58)		
INI, Week 24, n=94, 94	3.9 (± 9.26)	-1.8 (± 10.38)		
INI, Week 28, n=89, 93	3.1 (± 11.02)	-1.6 (± 9.55)		
INI, Week 32, n=92, 95	3.0 (± 10.40)	-2.0 (± 9.69)		
INI, Week 36, n=94, 95	3.7 (± 11.19)	-2.3 (± 9.30)		
INI, Week 40, n=89, 95	2.7 (± 10.45)	-2.6 (± 10.14)		
INI, Week 44, n=91, 94	2.6 (± 9.88)	-1.6 (± 10.90)		
INI, Week 48, n=90, 94	3.0 (± 9.74)	-1.6 (± 9.73)		
NNRTI, Week 4, n=151, 153	-3.4 (± 9.06)	-2.3 (± 8.10)		
NNRTI, Week 8, n=121, 152	-1.1 (± 9.35)	-1.3 (± 7.72)		
NNRTI, Week 12, n=146, 152	-1.7 (± 8.90)	-0.5 (± 7.03)		
NNRTI, Week 16, n=143, 148	-1.8 (± 10.60)	-2.3 (± 9.06)		
NNRTI, Week 20, n=138, 152	-3.7 (± 9.64)	-1.9 (± 7.41)		
NNRTI, Week 24, n=142, 151	-4.3 (± 10.67)	-2.0 (± 7.67)		
NNRTI, Week 28, n=136, 150	-4.3 (± 10.68)	-2.4 (± 8.67)		
NNRTI, Week 32, n=137, 148	-3.3 (± 10.42)	-2.8 (± 8.80)		
NNRTI, Week 36, n=135, 147	-3.8 (± 10.97)	-2.5 (± 8.16)		
NNRTI, Week 40, n=137, 147	-4.4 (± 9.97)	-2.0 (± 8.90)		
NNRTI, Week 44, n=136, 148	-4.4 (± 9.75)	-2.0 (± 7.45)		
NNRTI, Week 48, n=131, 147	-5.2 (± 11.72)	-1.6 (± 8.25)		

Notes:

[131] - Safety Population

[132] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Lipase

End point title	Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Lipase

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: lipase to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[133]	308[134]		
Units: Units per liter				
arithmetic mean (standard deviation)				
PI, Week 4, n=51, 53	-2.2 (± 16.83)	1.2 (± 19.34)		
PI, Week 8, n=34, 53	-2.6 (± 6.71)	2.5 (± 25.36)		
PI, Week 12, n=49, 52	-1.4 (± 17.24)	-2.2 (± 15.95)		
PI, Week 16, n=47, 53	-0.5 (± 18.71)	1.4 (± 17.40)		
PI, Week 20, n=46, 53	-2.5 (± 17.90)	-0.6 (± 17.49)		
PI, Week 24, n=47, 53	-2.0 (± 16.61)	-2.7 (± 16.30)		
PI, Week 28, n=42, 53	-0.7 (± 18.60)	0.2 (± 16.18)		
PI, Week 32, n=45, 51	-2.2 (± 19.27)	2.5 (± 18.35)		
PI, Week 36, n=44, 50	-0.8 (± 17.96)	-1.2 (± 18.18)		
PI, Week 40, n=42, 51	2.2 (± 26.77)	-1.8 (± 19.40)		
PI, Week 44, n=47, 51	-1.2 (± 18.28)	1.4 (± 17.94)		
PI, Week 48, n=43, 50	-1.5 (± 19.38)	-1.3 (± 15.73)		
INI, Week 4, n=99, 97	8.1 (± 34.32)	3.8 (± 30.44)		
INI, Week 8, n=72, 98	0.7 (± 9.79)	-0.5 (± 14.46)		
INI, Week 12, n=99, 93	4.3 (± 17.70)	1.8 (± 21.29)		
INI, Week 16, n=93, 97	4.4 (± 22.42)	0.6 (± 16.13)		
INI, Week 20, n=94, 97	2.5 (± 17.23)	0.9 (± 17.07)		
INI, Week 24, n=94, 95	2.2 (± 15.17)	2.2 (± 18.91)		
INI, Week 28, n=89, 94	5.6 (± 28.06)	5.1 (± 24.20)		
INI, Week 32, n=92, 95	3.2 (± 18.68)	5.4 (± 22.79)		
INI, Week 36, n=94, 95	5.2 (± 21.04)	0.1 (± 13.82)		
INI, Week 40, n=89, 95	3.5 (± 11.71)	1.7 (± 16.60)		
INI, Week 44, n=91, 94	4.3 (± 21.59)	4.8 (± 23.54)		
INI, Week 48, n=90, 94	5.0 (± 24.95)	3.9 (± 23.48)		
NNRTI, Week 4, n=151, 153	5.7 (± 50.44)	0.1 (± 20.35)		
NNRTI, Week 8, n=121, 152	2.6 (± 25.04)	1.5 (± 16.94)		

NNRTI, Week 12, n=146, 152	3.0 (± 30.94)	-1.9 (± 17.59)		
NNRTI, Week 16, n=145, 149	2.5 (± 27.82)	6.1 (± 40.62)		
NNRTI, Week 20, n=138, 152	0.9 (± 13.53)	1.3 (± 37.14)		
NNRTI, Week 24, n=142, 151	3.4 (± 24.81)	5.4 (± 28.22)		
NNRTI, Week 28, n=136, 150	0.8 (± 24.38)	1.2 (± 15.79)		
NNRTI, Week 32, n=137, 148	9.1 (± 78.96)	1.9 (± 21.30)		
NNRTI, Week 36, n=135, 147	6.9 (± 68.07)	1.7 (± 19.14)		
NNRTI, Week 40, n=138, 147	7.1 (± 43.53)	0.5 (± 17.62)		
NNRTI, Week 44, n=136, 148	1.6 (± 24.46)	1.1 (± 20.52)		
NNRTI, Week 48, n=131, 146	3.1 (± 32.54)	0.9 (± 16.60)		

Notes:

[133] - Safety Population

[134] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48

End point title	Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: CO2, chloride, glucose, phosphate, potassium, sodium and urea to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value.Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[135]	308[136]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
PI, CO2, Week 4, n=51, 53	1.3 (± 2.63)	0.7 (± 2.34)		
PI, CO2, Week 8, n=34, 53	0.4 (± 2.36)	0.3 (± 2.65)		
PI, CO2, Week 12, n=50, 52	0.7 (± 2.84)	0.2 (± 2.23)		
PI, CO2, Week 16, n=48, 53	0.8 (± 2.60)	0.2 (± 2.32)		
PI, CO2, Week 20, n=46, 53	0.9 (± 2.53)	0.0 (± 2.26)		
PI, CO2, Week 24, n=47, 53	0.4 (± 2.23)	0.1 (± 1.94)		
PI, CO2, Week 28, n=42, 53	0.6 (± 2.54)	-0.2 (± 2.37)		
PI, CO2, Week 32, n=45, 51	0.5 (± 2.35)	-0.2 (± 2.36)		
PI, CO2, Week 36, n=44, 50	0.5 (± 2.38)	-0.4 (± 1.98)		
PI, CO2, Week 40, n=42, 51	0.5 (± 2.10)	0.3 (± 2.26)		
PI, CO2, Week 44, n=47, 51	0.7 (± 2.29)	0.3 (± 2.18)		
PI, CO2, Week 48, n=43, 50	0.9 (± 2.69)	-0.1 (± 1.87)		

INI, CO2, Week 4, n=99, 97	1.0 (± 2.37)	0.8 (± 2.21)		
INI, CO2, Week 8, n=73, 98	0.5 (± 2.29)	0.6 (± 2.46)		
INI, CO2, Week 12, n=99, 95	0.4 (± 2.27)	0.3 (± 2.31)		
INI, CO2, Week 16, n=93, 96	0.1 (± 2.56)	0.6 (± 2.53)		
INI, CO2, Week 20, n=93, 97	0.1 (± 2.07)	0.7 (± 2.25)		
INI, CO2, Week 24, n=94, 95	0.1 (± 2.32)	0.2 (± 2.49)		
INI, CO2, Week 28, n=89, 93	-0.3 (± 2.30)	0.2 (± 2.41)		
INI, CO2, Week 32, n=93, 95	0.2 (± 2.33)	0.1 (± 2.34)		
INI, CO2, Week 36, n=94, 95	0.0 (± 2.36)	0.5 (± 2.58)		
INI, CO2, Week 40, n=90, 95	0.5 (± 2.43)	0.3 (± 2.18)		
INI, CO2, Week 44, n=91, 94	0.5 (± 2.36)	0.7 (± 2.45)		
INI, CO2, Week 48, n=91, 95	0.1 (± 2.12)	0.3 (± 2.53)		
NNRTI, CO2, Week 4, n=151, 153	0.9 (± 2.60)	0.7 (± 2.18)		
NNRTI, CO2, Week 8, n=122, 152	0.4 (± 2.32)	0.8 (± 2.52)		
NNRTI, CO2, Week 12, n=146, 152	0.5 (± 2.38)	0.4 (± 2.51)		
NNRTI, CO2, Week 16, n=143, 149	0.3 (± 2.25)	0.5 (± 2.37)		
NNRTI, CO2, Week 20, n=138, 152	0.1 (± 2.27)	0.2 (± 2.35)		
NNRTI, CO2, Week 24, n=143, 150	0.3 (± 2.63)	0.3 (± 2.57)		
NNRTI, CO2, Week 28, n=136, 150	0.1 (± 2.54)	0.2 (± 2.40)		
NNRTI, CO2, Week 32, n=137, 148	-0.2 (± 2.39)	0.4 (± 2.27)		
NNRTI, CO2, Week 36, n=135, 147	0.1 (± 2.38)	0.5 (± 2.37)		
NNRTI, CO2, Week 40, n=138, 147	0.4 (± 2.64)	0.5 (± 2.38)		
NNRTI, CO2, Week 44, n=137, 148	0.4 (± 2.35)	0.5 (± 2.01)		
NNRTI, CO2, Week 48, n=131, 147	-0.1 (± 2.47)	0.3 (± 2.30)		
PI, Chloride, Week 4, n=51, 53	0.5 (± 1.80)	0.5 (± 2.34)		
PI, Chloride, Week 8, n=34, 53	0.2 (± 2.59)	0.7 (± 2.42)		
PI, Chloride, Week 12, n=50, 52	0.5 (± 2.39)	0.8 (± 2.20)		
PI, Chloride, Week 16, n=48, 53	0.5 (± 2.46)	1.0 (± 2.31)		
PI, Chloride, Week 20, n=46, 53	0.8 (± 2.20)	0.7 (± 2.30)		
PI, Chloride, Week 24, n=47, 53	1.1 (± 2.07)	1.3 (± 2.36)		
PI, Chloride, Week 28, n=42, 53	1.5 (± 2.19)	1.2 (± 3.06)		
PI, Chloride, Week 32, n=45, 51	0.9 (± 2.43)	0.9 (± 2.60)		
PI, Chloride, Week 36, n=44, 50	1.0 (± 2.28)	1.0 (± 3.00)		
PI, Chloride, Week 40, n=42, 51	1.3 (± 2.35)	1.1 (± 2.60)		
PI, Chloride, Week 44, n=47, 51	1.1 (± 2.21)	1.1 (± 2.57)		
PI, Chloride, Week 48, n=43, 50	0.5 (± 2.10)	0.9 (± 2.29)		
INI, Chloride, Week 4, n=99, 97	0.3 (± 2.02)	0.5 (± 1.96)		
INI, Chloride, Week 8, n=73, 98	0.2 (± 2.02)	0.1 (± 2.42)		
INI, Chloride, Week 12, n=99, 95	0.4 (± 2.53)	0.5 (± 2.27)		
INI, Chloride, Week 16, n=93, 96	0.9 (± 2.45)	0.7 (± 2.32)		
INI, Chloride, Week 20, n=93, 97	1.0 (± 2.44)	0.2 (± 2.31)		
INI, Chloride, Week 24, n=94, 95	0.6 (± 2.46)	0.5 (± 2.19)		
INI, Chloride, Week 28, n=89, 93	0.8 (± 1.92)	0.3 (± 2.37)		
INI, Chloride, Week 32, n=93, 95	0.7 (± 2.39)	0.7 (± 2.45)		
INI, Chloride, Week 36, n=94, 95	0.8 (± 2.20)	0.5 (± 2.32)		
INI, Chloride, Week 40, n=90, 95	0.7 (± 2.24)	0.4 (± 2.69)		
INI, Chloride, Week 44, n=91, 94	0.7 (± 2.38)	0.5 (± 2.41)		
INI, Chloride, Week 48, n=91, 95	0.4 (± 2.37)	-0.3 (± 2.36)		
NNRTI, Chloride, Week 4, n=151, 153	0.4 (± 2.15)	0.6 (± 2.17)		
NNRTI, Chloride, Week 8, n=122, 152	0.4 (± 2.05)	0.7 (± 1.91)		
NNRTI, Chloride, Week 12, n=146, 152	0.4 (± 2.12)	0.5 (± 2.27)		
NNRTI, Chloride, Week 16, n=143, 149	0.5 (± 2.37)	0.8 (± 2.20)		

NNRTI, Chloride, Week 20, n=138, 152	0.7 (± 2.27)	1.1 (± 2.40)		
NNRTI, Chloride, Week 24, n=143, 151	0.5 (± 2.60)	1.1 (± 2.24)		
NNRTI, Chloride, Week 28, n=136, 150	0.8 (± 2.38)	1.3 (± 2.39)		
NNRTI, Chloride, Week 32, n=137, 148	0.8 (± 2.44)	1.1 (± 2.15)		
NNRTI, Chloride, Week 36, n=135, 147	1.0 (± 2.15)	1.1 (± 2.37)		
NNRTI, Chloride, Week 40, n=138, 147	0.6 (± 2.20)	1.0 (± 2.84)		
NNRTI, Chloride, Week 44, n=137, 148	0.6 (± 2.07)	1.0 (± 2.08)		
NNRTI, Chloride, Week 48, n=131, 147	0.6 (± 2.45)	0.5 (± 2.36)		
PI, Glucose, Week 4, n=43, 43	-0.08 (± 0.922)	0.32 (± 0.401)		
PI, Glucose, Week 8, n=25, 41	0.17 (± 0.513)	0.22 (± 0.466)		
PI, Glucose, Week 12, n=40, 42	0.03 (± 0.925)	0.27 (± 0.494)		
PI, Glucose, Week 16, n=39, 43	0.11 (± 1.163)	0.28 (± 0.704)		
PI, Glucose, Week 20, n=35, 41	-0.07 (± 1.058)	0.30 (± 0.799)		
PI, Glucose, Week 24, n=38, 42	0.11 (± 0.705)	0.32 (± 0.636)		
PI, Glucose, Week 28, n=32, 43	-0.03 (± 1.342)	0.16 (± 0.441)		
PI, Glucose, Week 32, n=36, 41	0.23 (± 1.148)	0.29 (± 0.600)		
PI, Glucose, Week 36, n=35, 41	-0.01 (± 1.014)	0.22 (± 0.483)		
PI, Glucose, Week 40, n=34, 40	0.11 (± 1.035)	0.18 (± 0.497)		
PI, Glucose, Week 44, n=40, 40	0.01 (± 1.008)	0.20 (± 0.278)		
PI, Glucose, Week 48, n=39, 48	-0.01 (± 0.977)	0.11 (± 0.663)		
INI, Glucose, Week 4, n=55, 52	0.30 (± 0.613)	0.07 (± 0.774)		
INI, Glucose, Week 8, n=36, 57	0.12 (± 0.595)	0.21 (± 1.083)		
INI, Glucose, Week 12, n=52, 55	0.36 (± 0.996)	0.30 (± 1.357)		
INI, Glucose, Week 16, n=53, 52	0.35 (± 1.437)	0.13 (± 0.557)		
INI, Glucose, Week 20, n=51, 57	0.25 (± 0.515)	-0.06 (± 0.676)		
INI, Glucose, Week 24, n=59, 61	0.24 (± 0.596)	0.04 (± 0.652)		
INI, Glucose, Week 28, n=52, 62	0.17 (± 0.681)	0.33 (± 0.763)		
INI, Glucose, Week 32, n=53, 55	0.48 (± 1.071)	0.32 (± 0.876)		
INI, Glucose, Week 36, n=53, 57	0.34 (± 0.642)	0.19 (± 1.063)		
INI, Glucose, Week 40, n=59, 62	0.36 (± 0.922)	0.14 (± 0.566)		
INI, Glucose, Week 44, n=54, 57	0.33 (± 0.971)	0.16 (± 0.626)		
INI, Glucose, Week 48, n=81, 90	0.04 (± 0.577)	-0.03 (± 0.796)		
NNRTI, Glucose, Week 4, n=116, 124	0.20 (± 0.666)	0.24 (± 1.055)		
NNRTI, Glucose, Week 8, n=90, 116	0.27 (± 0.987)	0.23 (± 0.795)		
NNRTI, Glucose, Week 12, n=112, 119	0.16 (± 0.746)	0.11 (± 0.887)		
NNRTI, Glucose, Week 16, n=115, 116	0.22 (± 0.767)	0.33 (± 1.347)		
NNRTI, Glucose, Week 20, n=106, 118	0.25 (± 0.636)	0.28 (± 1.104)		
NNRTI, Glucose, Week 24, n=115, 121	0.27 (± 0.763)	0.16 (± 1.037)		
NNRTI, Glucose, Week 28, n=104, 120	0.23 (± 0.596)	0.30 (± 1.077)		
NNRTI, Glucose, Week 32, n=103, 117	0.32 (± 0.811)	0.24 (± 1.062)		
NNRTI, Glucose, Week 36, n=102, 117	0.17 (± 0.789)	0.31 (± 1.217)		
NNRTI, Glucose, Week 40, n=100, 111	0.27 (± 0.692)	0.33 (± 1.118)		
NNRTI, Glucose, Week 44, n=99, 116	0.26 (± 0.793)	0.35 (± 1.121)		
NNRTI, Glucose, Week 48, n=118, 136	0.06 (± 0.659)	0.02 (± 1.074)		
PI, Phosphate, Week 4, n=51, 53	0.068 (± 0.1513)	0.009 (± 0.1682)		
PI, Phosphate, Week 8, n=34, 53	0.076 (± 0.2023)	-0.019 (± 0.1752)		

PI, Phosphate, Week 12, n=50, 52	0.025 (± 0.1794)	0.007 (± 0.1524)		
PI, Phosphate, Week 16, n=48, 53	0.056 (± 0.2028)	-0.008 (± 0.1610)		
PI, Phosphate, Week 20, n=46, 53	0.069 (± 0.1864)	0.017 (± 0.1924)		
PI, Phosphate, Week 24, n=47, 53	0.037 (± 0.1971)	0.018 (± 0.1735)		
PI, Phosphate, Week 28, n=42, 53	0.035 (± 0.2140)	0.017 (± 0.1971)		
PI, Phosphate, Week 32, n=45, 51	0.053 (± 0.2191)	0.032 (± 0.1545)		
PI, Phosphate, Week 36, n=44, 50	0.032 (± 0.1818)	-0.001 (± 0.1828)		
PI, Phosphate, Week 40, n=42, 51	0.027 (± 0.2392)	0.001 (± 0.1657)		
PI, Phosphate, Week 44, n=47, 51	0.033 (± 0.2107)	0.011 (± 0.1736)		
PI, Phosphate, Week 48, n=43, 50	0.048 (± 0.1994)	0.017 (± 0.1387)		
INI, Phosphate, Week 4, n=99, 97	0.036 (± 0.1518)	0.017 (± 0.1588)		
INI, Phosphate, Week 8, n=73, 98	0.056 (± 0.1532)	0.010 (± 0.1676)		
INI, Phosphate, Week 12, n=99, 95	0.024 (± 0.2108)	0.017 (± 0.1808)		
INI, Phosphate, Week 16, n=93, 96	0.031 (± 0.1895)	0.001 (± 0.1708)		
INI, Phosphate, Week 20, n=93, 97	0.012 (± 0.1764)	0.025 (± 0.1823)		
INI, Phosphate, Week 24, n=94, 95	0.031 (± 0.1501)	-0.011 (± 0.1785)		
INI, Phosphate, Week 28, n=89, 93	0.032 (± 0.1628)	0.006 (± 0.1806)		
INI, Phosphate, Week 32, n=93, 95	0.012 (± 0.1751)	-0.017 (± 0.1827)		
INI, Phosphate, Week 36, n=94, 95	-0.002 (± 0.1496)	-0.001 (± 0.1979)		
INI, Phosphate, Week 40, n=90, 95	0.018 (± 0.1766)	-0.002 (± 0.1721)		
INI, Phosphate, Week 44, n=91, 94	0.005 (± 0.1695)	0.005 (± 0.1977)		
INI, Phosphate, Week 48, n=91, 95	0.028 (± 0.1684)	0.002 (± 0.2072)		
NNRTI, Phosphate, Week 4, n=151, 153	0.085 (± 0.1785)	0.016 (± 0.1580)		
NNRTI, Phosphate, Week 8, n=122, 152	0.061 (± 0.2002)	-0.012 (± 0.1515)		
NNRTI, Phosphate, Week 12, n=146, 152	0.057 (± 0.1946)	0.012 (± 0.1780)		
NNRTI, Phosphate, Week 16, n=143, 149	0.043 (± 0.2088)	0.008 (± 0.1613)		
NNRTI, Phosphate, Week 20, n=138, 152	0.039 (± 0.1935)	-0.002 (± 0.1823)		
NNRTI, Phosphate, Week 24, n=143, 151	0.050 (± 0.2220)	0.012 (± 0.1923)		
NNRTI, Phosphate, Week 28, n=136, 150	0.040 (± 0.1850)	-0.003 (± 0.1789)		
NNRTI, Phosphate, Week 32, n=137, 148	0.018 (± 0.2056)	0.011 (± 0.2020)		
NNRTI, Phosphate, Week 36, n=135, 147	0.014 (± 0.2069)	-0.002 (± 0.1794)		

NNRTI, Phosphate, Week 40, n=138, 147	0.026 (± 0.2095)	-0.006 (± 0.1783)		
NNRTI, Phosphate, Week 44, n=137, 148	0.041 (± 0.2112)	0.000 (± 0.1735)		
NNRTI, Phosphate, Week 48, n=131, 147	0.034 (± 0.2220)	-0.001 (± 0.1619)		
PI, Potassium, Week 4, n=51, 53	0.12 (± 0.369)	0.20 (± 0.447)		
PI, Potassium, Week 8, n=34, 53	0.05 (± 0.245)	0.08 (± 0.307)		
PI, Potassium, Week 12, n=50, 52	0.12 (± 0.353)	0.19 (± 0.388)		
PI, Potassium, Week 16, n=48, 53	0.02 (± 0.343)	0.19 (± 0.398)		
PI, Potassium, Week 20, n=46, 53	0.05 (± 0.338)	0.18 (± 0.420)		
PI, Potassium, Week 24, n=47, 53	0.01 (± 0.354)	0.19 (± 0.384)		
PI, Potassium, Week 28, n=42, 53	0.09 (± 0.338)	0.15 (± 0.342)		
PI, Potassium, Week 32, n=45, 51	0.02 (± 0.356)	0.19 (± 0.408)		
PI, Potassium, Week 36, n=44, 50	0.12 (± 0.363)	0.14 (± 0.371)		
PI, Potassium, Week 40, n=42, 51	0.09 (± 0.348)	0.15 (± 0.394)		
PI, Potassium, Week 44, n=47, 51	0.10 (± 0.409)	0.21 (± 0.433)		
PI, Potassium, Week 48, n=43, 50	0.02 (± 0.359)	0.01 (± 0.409)		
INI, Potassium, Week 4, n=99, 97	0.03 (± 0.308)	0.08 (± 0.335)		
INI, Potassium, Week 8, n=73, 98	-0.02 (± 0.282)	0.06 (± 0.483)		
INI, Potassium, Week 12, n=99, 95	0.02 (± 0.316)	0.01 (± 0.329)		
INI, Potassium, Week 16, n=93, 96	-0.01 (± 0.286)	0.01 (± 0.319)		
INI, Potassium, Week 20, n=93, 97	0.03 (± 0.333)	0.00 (± 0.313)		
INI, Potassium, Week 24, n=94, 95	0.02 (± 0.304)	0.04 (± 0.315)		
INI, Potassium,Week 28, n=89, 93	0.02 (± 0.422)	0.03 (± 0.372)		
INI, Potassium, Week 32, n=93, 95	0.02 (± 0.322)	0.01 (± 0.289)		
INI, Potassium, Week 36, n=94, 95	0.01 (± 0.345)	0.05 (± 0.349)		
INI, Potassium, Week 40, n=90, 95	0.01 (± 0.288)	0.01 (± 0.329)		
INI, Potassium, Week 44, n=91, 94	0.01 (± 0.265)	0.00 (± 0.327)		
INI, Potassium, Week 48, n=91, 95	-0.03 (± 0.249)	-0.01 (± 0.292)		
NNRTI, Potassium, Week 4, n=151, 153	0.05 (± 0.354)	0.10 (± 0.368)		
NNRTI, Potassium, Week 8, n=122, 152	0.02 (± 0.342)	0.05 (± 0.355)		
NNRTI, Potassium, Week 12, n=146, 152	0.02 (± 0.351)	0.08 (± 0.353)		
NNRTI, Potassium, Week 16, n=143, 149	0.03 (± 0.373)	0.05 (± 0.320)		
NNRTI, Potassium,Week 20, n=138, 152	0.04 (± 0.358)	0.03 (± 0.355)		
NNRTI, Potassium, Week 24, n=143, 150	0.04 (± 0.329)	0.04 (± 0.324)		
NNRTI, Potassium, Week 28, n=136, 150	0.03 (± 0.364)	0.08 (± 0.412)		
NNRTI, Potassium, Week 32, n=137, 148	0.01 (± 0.442)	0.02 (± 0.348)		
NNRTI, Potassium, Week 36, n=135, 147	0.02 (± 0.359)	0.05 (± 0.360)		
NNRTI, Potassium, Week 40, n=138, 147	0.05 (± 0.375)	0.08 (± 0.342)		
NNRTI, Potassium, Week 44, n=137, 148	0.08 (± 0.364)	0.07 (± 0.366)		
NNRTI, Potassium, Week 48, n=131, 147	-0.02 (± 0.311)	0.00 (± 0.329)		
PI, Sodium, Week 4, n=51, 53	0.4 (± 1.93)	0.3 (± 2.11)		
PI, Sodium, Week 8, n=34, 53	0.9 (± 2.21)	0.3 (± 2.25)		
PI, Sodium, Week 12, n=50, 52	0.5 (± 2.09)	0.7 (± 1.97)		

PI, Sodium, Week 16, n=48, 53	0.5 (± 2.30)	0.3 (± 2.24)		
PI, Sodium, Week 20, n=46, 53	0.6 (± 2.15)	0.4 (± 2.12)		
PI, Sodium, Week 24, n=47, 53	0.5 (± 2.33)	0.4 (± 2.30)		
PI, Sodium, Week 28, n=42, 53	1.3 (± 2.06)	0.8 (± 2.75)		
PI, Sodium, Week 32, n=45, 51	0.5 (± 2.47)	0.5 (± 2.26)		
PI, Sodium, Week 36, n=44, 50	0.8 (± 2.21)	0.6 (± 2.63)		
PI, Sodium, Week 40, n=42, 51	0.8 (± 2.20)	0.7 (± 2.03)		
PI, Sodium, Week 44, n=47, 51	0.8 (± 2.10)	0.7 (± 2.49)		
PI, Sodium, Week 48, n=43, 50	0.9 (± 1.98)	0.8 (± 1.95)		
INI, Sodium, Week 4, n=99, 97	0.3 (± 1.62)	0.0 (± 1.97)		
INI, Sodium, Week 8, n=73, 98	0.1 (± 1.98)	-0.3 (± 1.87)		
INI, Sodium, Week 12, n=99, 95	0.3 (± 2.11)	0.0 (± 1.69)		
INI, Sodium, Week 16, n=93, 96	0.3 (± 1.95)	0.4 (± 1.97)		
INI, Sodium, Week 20, n=93, 97	0.5 (± 1.94)	0.1 (± 1.86)		
INI, Sodium, Week 24, n=94, 95	0.5 (± 1.79)	0.0 (± 1.73)		
INI, Sodium, Week 28, n=89, 93	0.5 (± 1.74)	-0.3 (± 1.93)		
INI, Sodium, Week 32, n=93, 95	0.5 (± 1.87)	0.2 (± 1.75)		
INI, Sodium, Week 36, n=94, 95	0.4 (± 1.86)	0.3 (± 1.88)		
INI, Sodium, Week 40, n=90, 95	0.5 (± 1.91)	0.2 (± 2.01)		
INI, Sodium, Week 44, n=91, 94	0.5 (± 1.77)	0.3 (± 1.93)		
INI, Sodium, Week 48, n=91, 95	0.4 (± 2.00)	-0.1 (± 1.85)		
NNRTI, Sodium, Week 4, n=151, 153	0.2 (± 1.95)	0.1 (± 1.98)		
NNRTI, Sodium, Week 8, n=122, 152	0.2 (± 1.91)	0.0 (± 1.82)		
NNRTI, Sodium, Week 12, n=146, 152	0.1 (± 2.04)	0.1 (± 2.01)		
NNRTI, Sodium, Week 16, n=143, 149	-0.1 (± 2.28)	-0.2 (± 2.04)		
NNRTI, Sodium, Week 20, n=138, 152	-0.1 (± 2.14)	0.3 (± 1.95)		
NNRTI, Sodium, Week 24, n=143, 151	0.1 (± 2.14)	0.3 (± 1.95)		
NNRTI, Sodium, Week 28, n=136, 150	0.3 (± 2.29)	0.2 (± 2.18)		
NNRTI, Sodium, Week 32, n=137, 148	0.1 (± 2.01)	0.5 (± 1.84)		
NNRTI, Sodium, Week 36, n=135, 147	0.4 (± 2.05)	0.5 (± 2.22)		
NNRTI, Sodium, Week 40, n=138, 147	0.3 (± 2.04)	0.5 (± 2.12)		
NNRTI, Sodium, Week 44, n=137, 148	0.5 (± 2.17)	0.5 (± 1.96)		
NNRTI, Sodium, Week 48, n=131, 147	0.3 (± 2.39)	0.4 (± 1.97)		
PI, Urea, Week 4, n=51, 53	0.02 (± 1.449)	0.01 (± 1.124)		
PI, Urea, Week 8, n=34, 53	0.21 (± 1.142)	-0.02 (± 1.205)		
PI, Urea, Week 12, n=50, 52	0.04 (± 1.446)	-0.01 (± 1.312)		
PI, Urea, Week 16, n=48, 53	0.25 (± 1.309)	0.20 (± 1.377)		
PI, Urea, Week 20, n=46, 53	0.18 (± 1.425)	0.17 (± 1.275)		
PI, Urea, Week 24, n=47, 53	0.41 (± 1.248)	0.10 (± 1.182)		
PI, Urea, Week 28, n=42, 53	0.18 (± 1.352)	0.00 (± 1.236)		
PI, Urea, Week 32, n=45, 51	0.12 (± 1.567)	0.16 (± 1.210)		
PI, Urea, Week 36, n=44, 50	0.01 (± 1.449)	-0.13 (± 1.190)		
PI, Urea, Week 40, n=42, 51	0.17 (± 1.291)	0.33 (± 1.714)		
PI, Urea, Week 44, n=47, 51	0.36 (± 1.258)	0.13 (± 1.276)		
PI, Urea, Week 48, n=43, 50	0.10 (± 1.303)	0.13 (± 1.305)		
INI, Urea, Week 4, n=99, 97	-0.14 (± 1.477)	0.19 (± 1.635)		
INI, Urea, Week 8, n=73, 98	-0.14 (± 1.799)	0.01 (± 1.601)		
INI, Urea, Week 12, n=99, 95	0.05 (± 1.554)	0.21 (± 1.481)		

INI, Urea, Week 16, n=93, 96	0.01 (± 1.402)	0.05 (± 1.375)		
INI, Urea, Week 20, n=93, 97	0.01 (± 1.531)	0.15 (± 1.495)		
INI, Urea, Week 24, n=94, 95	0.04 (± 1.367)	0.12 (± 1.441)		
INI, Urea, Week 28, n=89, 93	0.01 (± 1.570)	-0.02 (± 1.579)		
INI, Urea, Week 32, n=93, 95	-0.09 (± 1.592)	0.01 (± 1.522)		
INI, Urea, Week 36, n=94, 95	-0.10 (± 1.514)	-0.05 (± 1.478)		
INI, Urea, Week 40, n=90, 95	0.01 (± 1.519)	0.12 (± 1.469)		
INI, Urea, Week 44, n=91, 94	-0.16 (± 1.583)	-0.19 (± 1.721)		
INI, Urea, Week 48, n=91, 95	0.11 (± 1.633)	-0.05 (± 1.304)		
NNRTI, Urea, Week 4, n=151, 153	0.10 (± 1.265)	0.04 (± 1.185)		
NNRTI, Urea, Week 8, n=122, 152	0.16 (± 1.286)	0.01 (± 1.252)		
NNRTI, Urea, Week 12, n=146, 152	0.26 (± 1.290)	0.06 (± 1.344)		
NNRTI, Urea, Week 16, n=143, 149	0.07 (± 1.407)	0.28 (± 1.609)		
NNRTI, Urea, Week 20, n=138, 152	0.25 (± 1.296)	0.07 (± 1.507)		
NNRTI, Urea, Week 24, n=143, 151	0.33 (± 1.499)	0.18 (± 1.276)		
NNRTI, Urea, Week 28, n=136, 150	0.22 (± 1.549)	0.02 (± 1.422)		
NNRTI, Urea, Week 32, n=137, 148	0.41 (± 1.410)	0.06 (± 1.416)		
NNRTI, Urea, Week 36, n=135, 147	0.19 (± 1.339)	0.04 (± 1.392)		
NNRTI, Urea, Week 40, n=138, 147	0.32 (± 1.347)	-0.01 (± 1.339)		
NNRTI, Urea, Week 44, n=137, 148	0.25 (± 1.346)	0.10 (± 1.344)		
NNRTI, Urea, Week 48, n=131, 147	0.37 (± 1.389)	-0.02 (± 1.325)		

Notes:

[135] - Safety Population

[136] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for fasting lipid panel using baseline third agent treatment class overtime including Week 48

End point title	Change from Baseline values for fasting lipid panel using baseline third agent treatment class overtime including Week 48

End point description:

Blood samples were collected for the analysis of fasting lipid panel: triglycerides, total cholesterol, HDL cholesterol and LDL cholesterol to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[137]	308[138]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
PI, Triglycerides, Week 48, n=40, 45	-0.733 (± 1.5612)	0.060 (± 0.9960)		
INI, Triglycerides, Week 48, n=72, 77	-0.078 (± 0.4964)	-0.117 (± 0.8052)		
NNRTI, Triglycerides, Week 48, n=119, 120	-0.015 (± 0.6121)	-0.014 (± 0.6761)		
PI, Cholesterol, Week 48, n=40, 45	-0.06 (± 0.629)	0.06 (± 0.744)		
INI, Cholesterol, Week 48, n=72, 77	0.18 (± 0.614)	-0.12 (± 0.674)		
NNRTI, Cholesterol, Week 48, n=119, 120	0.06 (± 0.743)	-0.02 (± 0.626)		
PI, HDL cholesterol, Week 48, n=40, 45	0.130 (± 0.2272)	0.001 (± 0.3429)		
INI, HDL cholesterol, Week 48, n=72, 77	0.074 (± 0.2339)	-0.038 (± 0.2308)		
NNRTI, HDL cholesterol, Week 48, n=119, 120	-0.011 (± 0.2936)	0.028 (± 0.2577)		
PI, LDL cholesterol, Week 48, n=37, 43	0.075 (± 0.5774)	0.043 (± 0.5545)		
INI, LDL cholesterol, Week 48, n=71, 76	0.144 (± 0.4840)	-0.015 (± 0.5333)		
NNRTI, LDL cholesterol, Week 48, n=116, 119	0.078 (± 0.6885)	-0.040 (± 0.5246)		

Notes:

[137] - Safety Population

[138] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with genotypic resistance using baseline third agent through Week 48

End point title	Number of participants with genotypic resistance using baseline third agent through Week 48

End point description:

Plasma samples were collected from participants who met confirmed virologic withdrawal criteria to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Genotypic Resistance data for the following drugs: DTG, EVG, RAL, DLV, EFV, ETR, NVP, RPV, 3TC, ABC, FTC, TDF, ZDV, d4T, ddI, ATV, DRV, FPV, IDV, LPV, NFV, RTV, SQV and TPV in participants meeting CVF criteria has been presented. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

At the time of CVF

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[139]	4[140]		
Units: Participants				
PI, INI, DTG, resistant, n=1, 0	0	0		
PI, INI, DTG, resistance possible, n=1, 0	0	0		
PI, INI, DTG, sensitive, n=1, 0	1	0		
PI, INI, EVG, resistant, n=1, 0	0	0		
PI, INI, EVG, resistance possible, n=1, 0	0	0		
PI, INI, EVG, sensitive, n=1, 0	1	0		
PI, INI, RAL, resistant, n=1, 0	0	0		
PI, INI, RAL, resistance possible, n=1, 0	0	0		
PI, INI, RAL, sensitive, n=1, 0	1	0		
PI, NNRTI, DLV, resistant, n=1, 0	0	0		
PI, NNRTI, DLV, resistance possible, n=1, 0	0	0		
PI, NNRTI, DLV, sensitive, n=1, 0	1	0		
PI, NNRTI, EFV, resistant, n=1, 0	0	0		
PI, NNRTI, EFV, resistance possible, n=1, 0	0	0		
PI, NNRTI, EFV, sensitive, n=1, 0	1	0		
PI, NNRTI, ETR, resistant, n=1, 0	0	0		
PI, NNRTI, ETR, resistance possible, n=1, 0	0	0		
PI, NNRTI, ETR, sensitive, n=1, 0	1	0		
PI, NNRTI, NVP, resistant, n=1, 0	0	0		
PI, NNRTI, NVP, resistance possible, n=1, 0	0	0		
PI, NNRTI, NVP, sensitive, n=1, 0	1	0		
PI, NNRTI, RPV, resistant, n=1, 0	1	0		
PI, NNRTI, RPV, resistance possible, n=1, 0	0	0		
PI, NNRTI, RPV, sensitive, n=1, 0	0	0		
PI, NRTI, 3TC, resistant, n=1, 0	0	0		
PI, NNRTI, 3TC, resistance possible, n=1, 0	0	0		
PI, NRTI, 3TC, sensitive, n=1, 0	1	0		
PI, NRTI, ABC, resistant, n=1, 0	0	0		
PI, NRTI, ABC, resistance possible, n=1, 0	0	0		
PI, NRTI, ABC, sensitive, n=1, 0	1	0		
PI, NRTI, FTC, resistant, n=1, 0	0	0		
PI, NRTI, FTC, resistance possible, n=1, 0	0	0		
PI, NRTI, FTC, sensitive, n=1, 0	1	0		
PI, NRTI, TDF, resistant, n=1, 0	0	0		
PI, NRTI, TDF, resistance possible, n=1, 0	0	0		
PI, NRTI, TDF, sensitive, n=1, 0	1	0		
PI, NRTI, ZDV, resistant, n=1, 0	0	0		
PI, NRTI, ZDV, resistance possible, n=1, 0	0	0		
PI, NRTI, ZDV, sensitive, n=1, 0	1	0		
PI, NRTI, d4T, resistant, n=1, 0	0	0		

PI, NRTI, d4T, resistance possible, n=1, 0	0	0		
PI, NRTI, d4T, sensitive, n=1, 0	1	0		
PI, NRTI, ddI, resistant, n=1, 0	0	0		
PI, NRTI, ddI, resistance possible, n=1, 0	0	0		
PI, NRTI, ddI, sensitive, n=1, 0	1	0		
PI, PI, ATV, resistant, n=1, 0	0	0		
PI, PI, ATV, resistance possible, n=1, 0	0	0		
PI, PI, ATV, sensitive, n=1, 0	1	0		
PI, PI, ATV/r, resistant, n=1, 0	0	0		
PI, PI, ATV/r, resistance possible, n=1, 0	0	0		
PI, PI, ATV/r, sensitive, n=1, 0	1	0		
PI, PI, DRV/r, resistant, n=1, 0	0	0		
PI, PI, DRV/r, resistance possible, n=1, 0	0	0		
PI, PI, DRV/r, sensitive, n=1, 0	1	0		
PI, PI, FPV/r, resistant, n=1, 0	0	0		
PI, PI, FPV/r, resistance possible, n=1, 0	0	0		
PI, PI, FPV/r, sensitive, n=1, 0	1	0		
PI, PI, IDV/r, resistant, n=1, 0	0	0		
PI, PI, IDV/r, resistance possible, n=1, 0	0	0		
PI, PI, IDV/r, sensitive, n=1, 0	1	0		
PI, PI, LPV/r, resistant, n=1, 0	0	0		
PI, PI, LPV/r, resistance possible, n=1, 0	0	0		
PI, PI, LPV/r, sensitive, n=1, 0	1	0		
PI, PI, NFV, resistant, n=1, 0	0	0		
PI, PI, NFV, resistance possible, n=1, 0	0	0		
PI, PI, NFV, sensitive, n=1, 0	1	0		
PI, PI, RTV, resistant, n=1, 0	0	0		
PI, PI, RTV, resistance possible, n=1, 0	0	0		
PI, PI, RTV, sensitive, n=1, 0	1	0		
PI, PI, SQV/r, resistant, n=1, 0	0	0		
PI, PI, SQV/r, resistance possible, n=1, 0	0	0		
PI, PI, SQV/r, sensitive, n=1, 0	1	0		
PI, PI, TPV/r, resistant, n=1, 0	0	0		
PI, PI, TPV/r, resistance possible, n=1, 0	0	0		
PI, PI, TPV/r, sensitive, n=1, 0	1	0		
INI, INI, DTG, resistant, n=0, 3	0	0		
INI, INI, DTG, resistance possible, n=0, 3	0	0		
INI, INI, DTG, sensitive, n=0, 3	0	3		
INI, INI, EVG, resistant, n=0, 3	0	0		
INI, INI, EVG, resistance possible, n=0, 3	0	0		
INI, INI, EVG, sensitive, n=0, 3	0	3		
INI, INI, RAL, resistant, n=0, 3	0	0		
INI, INI, RAL, resistance possible, n=0, 3	0	0		
INI, INI, RAL, sensitive, n=0, 3	0	3		

INI, NNRTI, DLV, resistant, n=0, 3	0	0		
INI, INI, DLV, resistance possible, n=0, 3	0	0		
INI, NNRTI, DLV, sensitive, n=0, 3	0	3		
INI, NNRTI, EFV, resistant, n=0, 3	0	0		
INI, INI, EFV, resistance possible, n=0, 3	0	0		
INI, NNRTI, EFV, sensitive, n=0, 3	0	3		
INI, NNRTI, ETR, resistant,, n=0, 3	0	0		
INI, NNRTI, ETR, resistance possible, n=0, 3	0	0		
INI, NNRTI, ETR, sensitive, n=0, 3	0	3		
INI, NNRTI, NVP, resistant, n=0, 3	0	0		
INI, NNRTI, NVP, resistance possible, n=0, 3	0	0		
INI, NNRTI, NVP, sensitive, n=0, 3	0	3		
INI, NNRTI, RPV, resistant, n=0, 3	0	1		
INI, NNRTI, RPV, resistance possible, n=0, 3	0	0		
INI, NNRTI, RPV, sensitive, n=0, 3	0	2		
INI, NRTI, 3TC, resistant, n=0, 3	0	1		
INI, NNRTI, 3TC, resistance possible, n=0, 3	0	0		
INI, NRTI, 3TC, sensitive, n=0, 3	0	2		
INI, NRTI, ABC, resistant, n=0, 3	0	0		
INI, NRTI, ABC, resistance possible,, n=0, 3	0	0		
INI, NRTI, ABC, sensitive, n=0, 3	0	3		
INI, NRTI, FTC, resistant, n=0, 3	0	1		
INI, NRTI, FTC, resistance possible, n=0, 3	0	0		
INI, NRTI, FTC, sensitive, n=0, 3	0	2		
INI, NRTI, TDF, resistant, n=0, 3	0	0		
INI, NRTI, TDF, resistance possible, n=0, 3	0	0		
INI, NRTI, TDF, sensitive, n=0, 3	0	3		
INI, NRTI, ZDV, resistant, n=0, 3	0	0		
INI, NRTI, ZDV, resistance possible, n=0, 3	0	0		
INI, NRTI, ZDV, sensitive, n=0, 3	0	3		
INI, NRTI, d4T, resistant, n=0, 3	0	0		
INI, NRTI, d4T, resistance possible, n=0, 3	0	0		
INI, NRTI, d4T, sensitive, n=0, 3	0	3		
INI, NRTI, ddI, resistant, n=0, 3	0	0		
INI, NRTI, ddI, resistance possible, n=0, 3	0	1		
INI, NRTI, ddI, sensitive, n=0, 3	0	2		
INI, PI, ATV, resistant, n=0, 3	0	0		
INI, PI, ATV, resistance possible, n=0, 3	0	0		
INI, PI, ATV, sensitive, n=0, 3	0	3		
INI, PI, ATV/r, n=0, 3	0	0		
INI, PI, ATV/r, resistance possible, n=0, 3	0	0		
INI, PI, ATV/r, sensitive, n=0, 3	0	3		
INI, PI, DRV/r, resistant, n=0, 3	0	0		

INI, PI, DRV/r, resistance possible, n=0, 3	0	0		
INI, PI, DRV/r, sensitive, n=0, 3	0	3		
INI, PI, FPV/r, resistant, n=0, 3	0	0		
INI, PI, FPV/r, resistance possible, n=0, 3	0	0		
INI, PI, FPV/r, sensitive, n=0, 3	0	3		
INI, PI, IDV/r, resistant, n=0, 3	0	0		
INI, PI, IDV/r, resistance possible, n=0, 3	0	0		
INI, PI, IDV/r, sensitive, n=0, 3	0	3		
INI, PI, LPV/r, resistant, n=0, 3	0	0		
INI, PI, LPV/r, resistance possible, n=0, 3	0	0		
INI, PI, LPV/r, sensitive, n=0, 3	0	3		
INI, PI, NFV, resistant, n=0, 3	0	0		
INI, PI, NFV, resistance possible, n=0, 3	0	0		
INI, PI, NFV, sensitive, n=0, 3	0	3		
INI, PI, RTV, resistant, n=0, 3	0	0		
INI, PI, RTV, resistance possible, n=0, 3	0	0		
INI, PI, RTV, sensitive, n=0, 3	0	3		
INI, PI, SQV/r, resistant, n=0, 3	0	0		
INI, PI, SQV/r, resistance possible, n=0, 3	0	0		
INI, PI, SQV/r, sensitive, n=0, 3	0	3		
INI, PI, TPV/r, resistant, n=0, 3	0	0		
INI, PI, TPV/r, resistance possible, n=0, 3	0	0		
INI, PI, TPV/r, sensitive, n=0, 3	0	3		
NNRTI, INI, DTG, resistant, n=2, 1	0	0		
NNRTI, INI, DTG, resistance possible, n=2, 1	0	0		
NNRTI, INI, DTG, sensitive, n=2, 1	2	1		
NNRTI, INI, EVG, resistant, n=2, 1	1	0		
NNRTI, INI, EVG, resistance possible, n=2, 1	0	0		
NNRTI, INI, EVG, sensitive, n=2, 1	1	1		
NNRTI, INI, RAL, resistant, n=2, 1	1	0		
NNRTI, INI, RAL, resistance possible, n=2, 1	0	0		
NNRTI, INI, RAL, sensitive, n=2, 1	1	1		
NNRTI, NNRTI, DLV, resistant, n=2, 1	0	0		
NNRTI, INI, DLV, resistance possible, n=2, 1	0	0		
NNRTI, NNRTI, DLV, sensitive, n=2, 1	2	1		
NNRTI, NNRTI, EFV, resistant, n=2, 1	1	1		
NNRTI, INI, EFV, resistance possible, n=2, 1	0	0		
NNRTI, NNRTI, EFV, sensitive, n=2, 1	1	0		
NNRTI, NNRTI, ETR, resistant, n=2, 1	0	0		
NNRTI, NNRTI, ETR, resistance possible,n=2, 1	2	0		
NNRTI, NNRTI, ETR, sensitive, n=2, 1	0	1		
NNRTI, NNRTI, NVP, resistant, n=2, 1	1	1		
NNRTI, NNRTI, NVP, resistance possible, n=2, 1	0	0		

NNRTI, NNRTI, NVP, sensitive, n=2, 1	1	0		
NNRTI, NNRTI, RPV, resistant, n=2, 1	2	0		
NNRTI, NNRTI, RPV, resistance possible, n=2, 1	0	0		
NNRTI, NNRTI, RPV, sensitive, n=2, 1	0	1		
NNRTI, NRTI, 3TC, resistant, n=2, 1	0	1		
NNRTI, NNRTI, 3TC, resistance possible, n=2, 1	0	0		
NNRTI, NRTI, 3TC, sensitive, n=2, 1	2	0		
NNRTI, NRTI, ABC, resistant, n=2, 1	0	0		
NNRTI, NRTI, ABC, resistance possible, n=2, 1	0	0		
NNRTI, NRTI, ABC, sensitive, n=2, 1	2	1		
NNRTI, NRTI, FTC, resistant, n=2, 1	0	1		
NNRTI, NRTI, FTC, resistance possible, n=2, 1	0	0		
NNRTI, NRTI, FTC, sensitive, n=2, 1	2	0		
NNRTI, NRTI, TDF, resistant, n=2, 1	0	0		
NNRTI, NRTI, TDF, resistance possible, n=2, 1	0	0		
NNRTI, NRTI, TDF, sensitive, n=2, 1	2	1		
NNRTI, NRTI, ZDV, resistant, n=2, 1	0	0		
NNRTI, NRTI, ZDV, resistance possible, n=2, 1	0	0		
NNRTI, NRTI, ZDV, sensitive, n=2, 1	2	1		
NNRTI, NRTI, d4T, resistant, n=2, 1	0	0		
NNRTI, NRTI, d4T, resistance possible, n=2, 1	0	0		
NNRTI, NRTI, d4T, sensitive, n=2, 1	2	1		
NNRTI, NRTI, ddI, resistant, n=2, 1	0	0		
NNRTI, NRTI, ddI, resistance possible, n=2, 1	0	1		
NNRTI, NRTI, ddI, sensitive, n=2, 1	2	0		
NNRTI, PI, ATV, resistant, n=2, 1	1	0		
NNRTI, PI, ATV, resistance possible, n=2, 1	0	0		
NNRTI, PI, ATV, sensitive, n=2, 1	1	1		
NNRTI, PI, ATV/r, resistant, n=2, 1	0	0		
NNRTI, PI, ATV/r, resistance possible, n=2, 1	1	0		
NNRTI, PI, ATV/r, sensitive, n=2, 1	1	1		
NNRTI, PI, DRV/r, resistant, n=2, 1	0	0		
NNRTI, PI, DRV/r, resistance possible, n=2, 1	0	0		
NNRTI, PI, DRV/r, sensitive, n=2, 1	2	1		
NNRTI, PI, FPV/r, resistant, n=2, 1	0	0		
NNRTI, PI, FPV/r, resistance possible, n=2, 1	0	0		
NNRTI, PI, FPV/r, sensitive, n=2, 1	2	1		
NNRTI, PI, IDV/r, resistant, n=2, 1	0	0		
NNRTI, PI, IDV/r, resistance possible, n=2, 1	0	0		
NNRTI, PI, IDV/r, sensitive, n=2, 1	2	1		
NNRTI, PI, LPV/r, resistant, n=2, 1	0	0		
NNRTI, PI, LPV/r, resistance possible, n=2, 1	0	0		

NNRTI, PI, LPV/r, sensitive, n=2, 1	2	1		
NNRTI, PI, NFV, resistant, n=2, 1	1	0		
NNRTI, PI, NFV, resistance possible, n=2, 1	0	0		
NNRTI, PI, NFV, sensitive, n=2, 1	1	1		
NNRTI, PI, RTV, resistant, n=2, 1	0	0		
NNRTI, PI, RTV, resistance possible, n=2, 1	0	0		
NNRTI, PI, RTV, sensitive, n=2, 1	2	1		
NNRTI, PI, SQV/r, resistant, n=2, 1	0	0		
NNRTI, PI, SQV/r, resistance possible, n=2, 1	0	0		
NNRTI, PI, SQV/r, sensitive, n=2, 1	2	1		
NNRTI, PI, TPV/r, resistant, n=2, 1	0	0		
NNRTI, PI, TPV/r, resistance possible, n=2, 1	0	0		
NNRTI, PI, TPV/r, sensitive, n=2, 1	2	1		

Notes:

[139] - CVF Population

[140] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with phenotypic resistance using baseline third agent through Week 48

End point title	Number of participants with phenotypic resistance using baseline third agent through Week 48

End point description:

Plasma samples were collected from participants who met confirmed virologic withdrawal criteria to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI).Phenotypic Resistance data for the following drugs:CAB, DTG, EVG, RAL, DLV, EFV, ETR, NVP, RPV, 3TC, ABC, FTC, TDF, ZDV, d4T, ddI, ATV, DRV, FPV, IDV, LPV, NFV, RTV, SQV and TPV in participants meeting CVF criteria has been presented.Phenotypic resistance, partially sensitive, and Sensitive were defined based on FC value from Monogram as:resistance (FC>clinical higher cutoff/biologic cutoff), partially sensitive (FC <=clinical higher cutoff and > clinical lower cutoff), sensitive (FC <= clinical lower cutoff/biologic cutoff). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

At the time of CVF

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[141]	4[142]		
Units: Participants				
PI, INI, CAB, resistant , n=1, 0	0	0		
PI, INI, CAB, sensitive, n=1, 0	1	0		
PI, INI, DTG, resistant, n=1, 0	0	0		
PI, INI, DTG, partially sensitive, n=1, 0	0	0		
PI, INI, DTG, sensitive, n=1, 0	1	0		

PI, INI, EVG, resistant, n=1, 0	0	0		
PI, INI, EVG, sensitive, n=1, 0	1	0		
PI, INI, RAL, resistant, n=1, 0	0	0		
PI, INI, RAL, sensitive, n=1, 0	1	0		
PI, NNRTI, DLV, resistant, n=1, 0	0	0		
PI, NNRTI, DLV, sensitive, n=1, 0	1	0		
PI, NNRTI, EFV, resistant, n=1, 0	0	0		
PI, NNRTI, EFV, sensitive, n=1, 0	1	0		
PI, NNRTI, ETR, resistant, n=1, 0	0	0		
PI, NNRTI, ETR, partially sensitive, n=1, 0	0	0		
PI, NNRTI, ETR, sensitive, n=1, 0	1	0		
PI, NNRTI, NVP, resistant, n=1, 0	0	0		
PI, NNRTI, NVP, sensitive, n=1, 0	1	0		
PI, NNRTI, RPV, resistant, n=1, 0	1	0		
PI, NNRTI, RPV, sensitive, n=1, 0	0	0		
PI, NRTI, 3TC, resistant, n=1, 0	0	0		
PI, NRTI, 3TC, sensitive, n=1, 0	1	0		
PI, NRTI, ABC, resistant, n=1, 0	0	0		
PI, NRTI, ABC, partially sensitive, n=1, 0	0	0		
PI, NRTI, ABC, sensitive, n=1, 0	1	0		
PI, NRTI, FTC, resistant, n=1, 0	0	0		
PI, NRTI, FTC, sensitive, n=1, 0	1	0		
PI, NRTI, TDF, resistant, n=1, 0	0	0		
PI, NRTI, TDF, partially sensitive, n=1, 0	0	0		
PI, NRTI, TDF, sensitive, n=1, 0	1	0		
PI, NRTI, ZDV, resistant, n=1, 0	0	0		
PI, NRTI, ZDV, sensitive, n=1, 0	1	0		
PI, NRTI, d4T, resistant, n=1, 0	0	0		
PI, NRTI, d4T, sensitive, n=1, 0	1	0		
PI, NRTI, ddI, resistant, n=1, 0	0	0		
PI, NRTI, ddI, partially sensitive, n=1, 0	0	0		
PI, NRTI, ddI, sensitive, n=1, 0	1	0		
PI, PI, ATV, resistant, n=1, 0	0	0		
PI, PI, ATV, sensitive, n=1, 0	1	0		
PI, PI, DRV, resistant, n=1, 0	0	0		
PI, PI, DRV, partially sensitive, n=1, 0	0	0		
PI, PI, DRV, sensitive, n=1, 0	1	0		
PI, PI, FPV, resistant, n=1, 0	0	0		
PI, PI, FPV, partially sensitive, n=1, 0	0	0		
PI, PI, FPV, sensitive, n=1, 0	1	0		
PI, PI, IDV, resistant, n=1, 0	0	0		
PI, PI, IDV, sensitive, n=1, 0	1	0		
PI, PI, LPV, resistant, n=1, 0	0	0		
PI, PI, LPV, partially sensitive, n=1, 0	0	0		
PI, PI, LPV, sensitive, n=1, 0	1	0		
PI, PI, NFV, resistant, n=1, 0	0	0		
PI, PI, NFV, sensitive, n=1, 0	1	0		
PI, PI, RTV, resistant, n=1, 0	0	0		
PI, PI, RTV, sensitive, n=1, 0	1	0		
PI, PI, SQV, resistant, n=1, 0	0	0		

PI, PI, SQV, partially sensitive, n=1, 0	0	0		
PI, PI, SQV, sensitive, n=1, 0	1	0		
PI, PI, TPV, resistant, n=1, 0	0	0		
PI, PI, TPV, partially sensitive, n=1, 0	0	0		
PI, PI, TPV, sensitive, n=1, 0	1	0		
INI, INI, CAB, resistant , n=0, 3	0	0		
INI, INI, CAB, sensitive, n=0, 3	0	3		
INI, INI, DTG, resistant, n=0, 3	0	0		
INI, INI, DTG, partially sensitive, n=0, 3	0	0		
INI, INI, DTG, sensitive, n=0, 3	0	3		
INI, INI, EVG, resistant, n=0, 3	0	0		
INI, INI, EVG, sensitive, n=0, 3	0	3		
INI, INI, RAL, resistant, n=0, 3	0	0		
INI, INI, RAL, sensitive, n=0, 3	0	3		
INI, NNRTI, DLV, resistant, n=0, 3	0	0		
INI, NNRTI, DLV, sensitive, n=0, 3	0	3		
INI, NNRTI, EFV, resistant, n=0, 3	0	0		
INI, NNRTI, EFV, sensitive, n=0, 3	0	3		
INI, NNRTI, ETR, resistant, n=0, 3	0	0		
INI, NNRTI, ETR, partially sensitive, n=0, 3	0	0		
INI, NNRTI, ETR, sensitive, n=0, 3	0	3		
INI, NNRTI, NVP, resistant, n=0, 3	0	0		
INI, NNRTI, NVP, sensitive, n=0, 3	0	3		
INI, NNRTI, RPV, resistant, n=0, 3	0	0		
INI, NNRTI, RPV, sensitive, n=0, 3	0	3		
INI, NRTI, 3TC, resistant, n=0, 3	0	1		
INI, NRTI, 3TC, sensitive, n=0, 3	0	2		
INI, NRTI, ABC, resistant, n=0, 3	0	0		
INI, NRTI, ABC, partially sensitive, n=0, 3	0	0		
INI, NRTI, ABC, sensitive, n=0, 3	0	3		
INI, NRTI, FTC, resistant, n=0, 3	0	1		
INI, NRTI, FTC, sensitive, n=0, 3	0	2		
INI, NRTI, TDF, resistant, n=0, 3	0	0		
INI, NRTI, TDF, partially sensitive, n=0, 3	0	0		
INI, NRTI, TDF, sensitive, n=0, 3	0	3		
INI, NRTI, ZDV, resistant, n=0, 3	0	0		
INI, NRTI, ZDV, sensitive, n=0, 3	0	3		
INI, NRTI, d4T, resistant, n=0, 3	0	0		
INI, NRTI, d4T, sensitive, n=0, 3	0	3		
INI, NRTI, ddI, resistant, n=0, 3	0	0		
INI, NRTI, ddI, partially sensitive, n=0, 3	0	0		
INI, NRTI, ddI, sensitive, n=0, 3	0	3		
INI, PI, ATV, resistant, n=0, 3	0	0		
INI, PI, ATV, sensitive, n=0, 3	0	3		
INI, PI, DRV, resistant, n=0, 3	0	0		
INI, PI, DRV, partially sensitive, n=0, 3	0	0		
INI, PI, DRV, sensitive, n=0, 3	0	3		
INI, PI, FPV, resistant, n=0, 3	0	0		
INI, PI, FPV, partially sensitive, n=0, 3	0	0		

INI, PI, FPV, sensitive, n=0, 3	0	3		
INI, PI, IDV, resistant, n=0, 3	0	0		
INI, PI, IDV, sensitive, n=0, 3	0	3		
INI, PI, LPV, resistant, n=0, 3	0	0		
INI, PI, LPV, partially sensitive, n=0, 3	0	0		
INI, PI, LPV, sensitive, n=0, 3	0	3		
INI, PI, NFV, resistant, n=0, 3	0	0		
INI, PI, NFV, sensitive, n=0, 3	0	3		
INI, PI, RTV, resistant, n=0, 3	0	0		
INI, PI, RTV, sensitive, n=0, 3	0	3		
INI, PI, SQV, resistant, n=0, 3	0	0		
INI, PI, SQV, partially sensitive, n=0, 3	0	0		
INI, PI, SQV, sensitive, n=0, 3	0	3		
INI, PI, TPV, resistant, n=0, 3	0	0		
INI, PI, TPV, partially sensitive, n=0, 3	0	0		
INI, PI, TPV, sensitive, n=0, 3	0	3		
NNRTI, INI, CAB, resistant , n=2, 1	1	0		
NNRTI, INI, CAB, sensitive, n=2, 1	1	1		
NNRTI, INI, DTG, resistant, n=2, 1	0	0		
NNRTI, INI, DTG, partially sensitive, n=2, 1	0	0		
NNRTI, INI, DTG, sensitive, n=2, 1	2	1		
NNRTI, INI, EVG, resistant, n=2, 1	1	0		
NNRTI, INI, EVG, sensitive, n=2, 1	1	1		
NNRTI, INI, RAL, resistant, n=2, 1	1	0		
NNRTI, INI, RAL, sensitive, n=2, 1	1	1		
NNRTI, NNRTI, DLV, resistant, n=2, 0	2	0		
NNRTI, NNRTI, DLV, sensitive, n=2, 0	0	0		
NNRTI, NNRTI, EFV, resistant, n=2, 0	2	0		
NNRTI, NNRTI, EFV, sensitive, n=2, 0	0	0		
NNRTI, NNRTI, ETR, resistant, n=2, 0	0	0		
NNRTI, NNRTI, ETR, partially sensitive, n=2, 0	2	0		
NNRTI, NNRTI, ETR, sensitive, n=2, 0	0	0		
NNRTI, NNRTI, NVP, resistant, n=2, 0	2	0		
NNRTI, NNRTI, NVP, sensitive, n=2, 0	0	0		
NNRTI, NNRTI, RPV, resistant, n=2, 0	2	0		
NNRTI, NNRTI, RPV, sensitive, n=2, 0	0	0		
NNRTI, NRTI, 3TC, resistant, n=2, 0	0	0		
NNRTI, NRTI, 3TC, sensitive, n=2, 0	2	0		
NNRTI, NRTI, ABC, resistant, n=2, 0	0	0		
NNRTI, NRTI, ABC, partially sensitive, n=2, 0	0	0		
NNRTI, NRTI, ABC, sensitive, n=2, 0	2	0		
NNRTI, NRTI, FTC, resistant, n=2, 0	0	0		
NNRTI, NRTI, FTC, sensitive, n=2, 0	2	0		
NNRTI, NRTI, TDF, resistant, n=2, 0	0	0		
NNRTI, NRTI, TDF, partially sensitive, n=2, 0	0	0		
NNRTI, NRTI, TDF, sensitive, n=2, 0	2	0		
NNRTI, NRTI, ZDV, resistant, n=2, 0	1	0		
NNRTI, NRTI, ZDV, sensitive, n=2, 0	1	0		
NNRTI, NRTI, d4T, resistant, n=2, 0	0	0		

NNRTI, NRTI, d4T, sensitive, n=2, 0	2	0		
NNRTI, NRTI, ddI, resistant, n=2, 0	0	0		
NNRTI, NRTI, ddI, partially sensitive, n=2, 0	0	0		
NNRTI, NRTI, ddI, sensitive, n=2, 0	2	0		
NNRTI, PI, ATV, resistant, n=2, 0	0	0		
NNRTI, PI, ATV, sensitive, n=2, 0	2	0		
NNRTI, PI, DRV, resistant, n=2, 0	0	0		
NNRTI, PI, DRV, partially sensitive, n=2, 0	0	0		
NNRTI, PI, DRV, sensitive, n=2, 0	2	0		
NNRTI, PI, FPV, resistant, n=2, 0	0	0		
NNRTI, PI, FPV, partially sensitive, n=2, 0	0	0		
NNRTI, PI, FPV, sensitive, n=2, 0	2	0		
NNRTI, PI, IDV, resistant, n=2, 0	0	0		
NNRTI, PI, IDV, sensitive, n=2, 0	2	0		
NNRTI, PI, LPV, resistant, n=2, 0	0	0		
NNRTI, PI, LPV, partially sensitive, n=2, 0	0	0		
NNRTI, PI, LPV, sensitive, n=2, 0	2	0		
NNRTI, PI, NFV, resistant, n=2, 0	0	0		
NNRTI, PI, NFV, sensitive, n=2, 0	2	0		
NNRTI, PI, RTV, resistant, n=2, 0	0	0		
NNRTI, PI, RTV, sensitive, n=2, 0	2	0		
NNRTI, PI, SQV, resistant, n=2,0	0	0		
NNRTI, PI, SQV, partially sensitive, n=2, 0	0	0		
NNRTI, PI, SQV, sensitive, n=2, 0	2	0		
NNRTI, PI, TPV, resistant, n=2, 0	0	0		
NNRTI, PI, TPV, partially sensitive, n=2, 0	0	0		
NNRTI, PI, TPV, sensitive, n=2, 0	2	0		

Notes:

[141] - CVF Population

[142] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 5 in dimension scores using percerption of injection questionnaire (PIN)-Last Observation Carried Forward (LOCF) in Q4W arm

End point title	Change from Week 5 in dimension scores using percerption of injection questionnaire (PIN)-Last Observation Carried Forward (LOCF) in Q4W arm[143]

End point description:

PIN questionnaire explores bother of pain at injection site and injection site reactions (ISR),anxiety before and after injection, willingness to receive HIV injectable treatment, following visit and satisfaction with mode of treatment administration of individuals receiving injection and perceptions associated with receiving injections.This measure contains 21 items: pain at injection site, local site reactions, impact on functioning and willingness to pursue injectable treatment outside clinical trial. Scores range from 1 to 5; questions are phrased to ensure that 1:most favorable perception of vaccination, and 5:most unfavorable.Dimension scores include bother from ISR, leg movement, sleep and acceptability.Score of a domain is calculated as mean of all items with domain.Higher scores represent worse perception of injection.LOCF was primary method of analysis. Only those participants with data available at specified data points were analyzed(represented by n= X in category titles)

End point type	Secondary

End point timeframe:

Week 5 and at Weeks 41 and 48

Notes:

[143] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

End point values	CAB LA+RPV LA (Q4W)			
Subject group type	Reporting group			
Number of subjects analysed	296[144]			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Bother of ISRs, Week 41	-0.21 (± 0.532)			
Bother of ISRs, Week 48	-0.21 (± 0.524)			
Leg movement, Week 41	-0.52 (± 0.903)			
Leg movement, Week 48	-0.59 (± 0.950)			
Sleep, Week 41	-0.56 (± 0.877)			
Sleep, Week 48	-0.56 (± 0.937)			
Acceptance, Week 41	-0.49 (± 1.094)			
Acceptance, Week 48	-0.54 (± 1.080)			

Notes:

[144] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with extremely or very acceptable pain and local reaction: acceptability score on PIN questionnaire in Q4W arm

End point title	Percentage of participants with extremely or very acceptable pain and local reaction: acceptability score on PIN questionnaire in Q4W arm[145]

End point description:

PIN questionnaire explores bother of pain at injection site and injection site reactions (ISR),anxiety before and after injection, willingness to receive HIV injectable treatment, following visit and satisfaction with mode of treatment administration of individuals receiving injection and perceptions associated with receiving injections.This measure contains 21 items: pain at injection site, local site reactions, impact on functioning and willingness to pursue injectable treatment outside clinical trial. Scores range from 1 to 5; questions are phrased to ensure that 1:most favorable perception of vaccination, and 5:most unfavorable.Dimension scores include bother from ISR, leg movement, sleep and acceptability.Score of a domain is calculated as mean of all items with domain.Higher scores represent worse perception of injection.LOCF was primary method of analysis.Only those participants with data available at specified data points were analyzed(represented by n= X in category titles)

End point type	Secondary

End point timeframe:

Weeks 5, 41 and 48

Notes:

[145] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

End point values	CAB LA+RPV LA (Q4W)			
Subject group type	Reporting group			
Number of subjects analysed	308[146]			
Units: Percentage of participants				
number (not applicable)				
Local reaction, Week 5, total, n=296	141			
Local reaction,Week 5, very acceptable, n=296	77			
Local reaction, Week 5, moderate, n=296	54			
Local reaction, Week 5, little, n=296	15			
Local reaction, Week 5, not at all, n=296	9			
Pain, Week 5, total, n=296	86			
Pain, Week 5, very acceptable, n=296	103			
Pain, Week 5, moderate, n=296	59			
Pain, Week 5, little, n=296	29			
Pain, Week 5, not at all, n=296	19			
Local reaction, Week 41, total, n=300	188			
Local reaction, Week 41, very acceptable, n=300	77			
Local reaction, Week 41, moderate, n=300	24			
Local reaction, Week 41, little, n=300	6			
Local reaction, Week 41, not at all, n=300	5			
Pain, Week 41, total, n=300	166			
Pain, Week 41, very acceptable, n=300	85			
Pain, Week 41, moderate, n=300	31			
Pain, Week 41, little, n=300	12			
Pain, Week 41, not at all, n=300	6			
Local reaction, week 48, total, n=303	202			
Local reaction, Week 48, very acceptable, n=303	69			
Local reaction, Week 48, moderate, n=303	21			
Local reaction, Week 48, little, n=303	8			
Local reaction, Week 48, not at all, n=303	3			
Pain, Week 48, total, n=303	168			
Pain, Week 48, very acceptable, n=303	95			
Pain, Week 48, moderate, n=303	26			
Pain, Week 48, little, n=303	11			
Pain, Week 48, not at all, n=303	3			

Notes:

[146] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in life satisfaction (LISAT) using HIV/AIDs-targeted quality of life (HATQoL) questionnaire

End point title	Change from Baseline in life satisfaction (LISAT) using HIV/AIDs-targeted quality of life (HATQoL) questionnaire

End point description:

The HATQoL questionnaire was used to assess health related QoL (HRQoL). It comprises of three dimensions:LISAT, medication worries (MEDWO) and disclosure worries (DISWO).Total imputed value score for LISAT is calculated on a 0-100 scale using formula:LISAT 100=[100 divided by (20 minus 4)]*(LISAT minus 4). A response of 5 in LISAT score shows satisfaction all of time and 1 as none of time. The higher the score, the greater satisfaction to life and the less worry.Transformed dimension score for each domain was summarized and analyzed. LOCF was used as primary method of analysis. Measure type was considered as mean for adjusted mean and dispersion measure as 95% confidence interval (CI).Baseline value is defined as latest pre-treatment assessment with a non-missing value.Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed (represented by n= X in

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[147]	308[148]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 24, n=292, 291	1.0 (-0.6 to 2.6)	1.1 (-0.5 to 2.7)		
Week 48, n=292, 297	1.1 (-0.6 to 2.8)	0.1 (-1.6 to 1.7)		

Notes:

[147] - ITT-E Population

[148] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Treatment comparison at Week 24 for the groups CAB LA+ RPV LA and current ART is presented.

Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.944
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	-0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.2

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Treatment comparison at Week 48 for the groups CAB LA+ RPV LA and current ART is presented.	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.385
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	3.4

Secondary: Change from Baseline in HIV medication, MEDWO using HATQoL

End point title	Change from Baseline in HIV medication, MEDWO using HATQoL

End point description:

The HATQoL questionnaire was used to assess health related QoL (HRQoL). It comprises of three dimensions: LISAT, medication worries(MEDWO)and disclosure worries (DISWO). Total imputed value score for MEDWO is calculated on a 0-100 scale using formula: MEDWO 100=[100 divided by (20 minus 5)]*(MEDWO minus 5).A response of 1 in MEDWO score shows less medication worries all of time and 5 as none of time. Higher the score, the greater satisfaction to life and less worry. Transformed dimension score for each domain was summarized and analyzed. LOCF was primary method of analysis. Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed (represented by n= X in category titles)

End point type	Secondary

End point timeframe:

Baseline and at Weeks 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[149]	308[150]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 24, n=292, 290	4.2 (2.7 to 5.8)	-0.7 (-2.2 to 0.9)		
Week 48, n=292, 296	4.0 (2.3 to 5.7)	-2.4 (-4.1 to -0.8)		

Notes:

[149] - ITT-E Population

[150] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Treatment comparison at Week 24 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.8
upper limit	7.1

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Treatment comparison at Week 48 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	6.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	4
upper limit	8.8

Secondary: Change from Baseline in DISWO using HATQoL

End point title	Change from Baseline in DISWO using HATQoL

End point description:

The HATQoL questionnaire was used to assess the health related QoL (HRQoL). It comprises of three dimensions: LISAT, medication worries (MEDWO) and disclosure worries (DISWO). Total imputed value score for DISWO is calculated on a 0-100 scale using the formula: DISWO 100=[100 divided by (20 minus 5)]*(DISWO minus 5). A response of 1 in DISWO score shows less medication worries all of time and 5 as none of the time.Higher the score, the greater satisfaction to life and less worry.Transformed dimension score for each domain was summarized and analyzed.LOCF was used as primary method of analysis. Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value.Only those participants with data available at specified data points were analyzed (represented by n= X in category titles)

End point type	Secondary

End point timeframe:

Baseline and at Weeks 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[151]	308[152]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 24, n=291, 290	8.3 (5.6 to 11.0)	3.0 (0.3 to 5.8)		
Week 48, n=291, 296	4.6 (1.7 to 7.6)	2.6 (-0.3 to 5.6)		

Notes:

[151] - ITT-E Population

[152] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Treatment comparison at Week 24 for the groups CAB LA+ RPV LA and current ART is presented

Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.008
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	5.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	9.1

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Treatment comparison at Week 48 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.347
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	6.2

Secondary: Change from Baseline in health status using 12-item short form survey (SF-12)

End point title	Change from Baseline in health status using 12-item short form survey (SF-12)
End point description:	
The SF-12 questionnaire consists of 7 questions which measures degree of general health status and mental health distress. Each question is scored 0-5, except for question 2 scored 0-3. HRQoL using SF-12 for total score, physical component summary (PCS) and mental component summary (MCS) were assessed for two treatment groups.Missing Total or component scores was imputed using LOCF.PCS/MCS are calculated using computer software purchased from QualityMetric (http://www.qualitymetric.com).The higher the score, the better will be the health status.Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as latest pre-treatment assessment with a non-missing value.Change from Baseline value is calculated as value at post-dose visit minus Baseline value.Only those participants with data available at specified data points were analyzed (represented by n= X in category titles).	
End point type	Secondary
End point timeframe:	
Baseline and at Weeks 24 and 48	

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[153]	308[154]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Total score, Week 24, n=291, 289	0.0 (-0.3 to 0.4)	-0.2 (-0.5 to 0.1)		
Total score, Week 48, n=293, 296	-0.0 (-0.4 to 0.3)	0.0 (-0.3 to 0.4)		
MCS, Week 24, n=289, 286	0.288 (-0.579 to 1.155)	-0.388 (-1.259 to 0.484)		
MCS, Week 48, n=291, 293	0.260 (-0.638 to 1.158)	-0.375 (-1.270 to 0.520)		
PCS, Week 24, n=286, 288	0.650 (0.087 to 1.213)	-0.047 (-0.608 to 0.514)		
PCS, Week 48, n=288, 295	0.758 (0.184 to 1.332)	0.062 (-0.505 to 0.629)		

Notes:

[153] - ITT-E Population

[154] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Treatment comparison of SF-12 total scores at Week 24 for the groups CAB LA+ RPV LA and current ART is presented

Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.344
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.7

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Treatment comparison of SF-12 total scores at Week 48 for the groups CAB LA+ RPV LA and current ART is presented

Comparison groups	CAB LA+RPV LA (Q4W) v Current ART

Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.785
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	0.4

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
Treatment comparison of SF-12 MCS at Week 24 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.282
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.676
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.557
upper limit	1.909

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
Treatment comparison of SF-12 MCS at Week 48 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.327
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.635

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.637
upper limit	1.907

Statistical analysis title	Statistical Analysis 5
Statistical analysis description:	
Treatment comparison of SF-12 PCS at Week 24 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.086
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.697
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	1.494

Statistical analysis title	Statistical Analysis 6
Statistical analysis description:	
Treatment comparison of SF-12 PCS at Week 48 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.092
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.696
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.113
upper limit	1.505

Secondary: Change from Baseline in total treatment satisfaction using HIV treatment satisfaction questionnaire (HIVTSQs) at Weeks 4b, 24 and 44

End point title	Change from Baseline in total treatment satisfaction using HIV

	treatment satisfaction questionnaire (HIVTSQs) at Weeks 4b, 24 and 44

End point description:

HIVTSQ total treatment satisfaction score is computed with 1-11 items. Items 1-11 are summed to produce score with possible range:-33 to 33.Item12 in scale calculated as individual score. Higher the score, greater improvement in satisfaction with treatment; lower score, greater the deterioration in satisfaction with treatment. A score of 0 represents no change. A maximum of 5 items can be missing, Missing scores are imputed with mean of completed item scores. If 6 or more items are missing, overall treatment satisfaction score should not be computed and will remain missing. LOCF was primary method of analysis. Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Data is presented with respect to actual treatment received by participants. Only those participants with data available at specified data points were analyzed(represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline and at Weeks 4b, 24 and 44

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[155]	308[156]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 4b, n=295, 0	3.99 (± 8.982)	99999 (± 99999)		
Week 24, n=300, 288	6.39 (± 10.328)	1.08 (± 8.510)		
Week 44, n=300, 294	6.02 (± 10.808)	0.54 (± 9.877)		

Notes:

[155] - ITT-E Population. 99999 indicates data not available due to insufficient participants

[156] - ITT-E Population. 99999 indicates data not available due to insufficient participants

Statistical analyses

No statistical analyses for this end point

Secondary: Change in treatment satisfaction over time using HIVTSQ change (HIVTSQc) at Week 48 in Q4W arm

End point title	Change in treatment satisfaction over time using HIVTSQ change (HIVTSQc) at Week 48 in Q4W arm[157]

End point description:

The HIVTSQtotal treatment satisfaction score is computed with 1-11 items.These 1-11 items are summed to produce score with possible range:-33 to 33.Item12 in scale calculated as individual score.Higher the score,greater improvement in satisfaction with treatment;lower score,greater the deterioration in satisfaction with treatment.A score of 0 represents no change.A maximum of 5 items can be missing,missing scores are imputed with mean of completed item scores.If 6or more items are missing,overall treatment satisfaction score should not be computed and will remain missing.LOCF was primary method of analysis.Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value.Data has been presented with respect to actual treatment received to the participants.Only those participants with data available at specified data points were analyzed

End point type	Secondary

End point timeframe:

Week 48

Notes:

[157] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

End point values	CAB LA+RPV LA (Q4W)			
Subject group type	Reporting group			
Number of subjects analysed	275[158]			
Units: Scores on a scale				
arithmetic mean (standard deviation)	29.05 (± 6.978)			

Notes:

[158] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in treatment acceptance at Weeks 8, 24 and 48 using "General acceptance" dimension of the Chronic Treatment Acceptance (ACCEPT) questionnaire

End point title	Change from Baseline in treatment acceptance at Weeks 8, 24 and 48 using "General acceptance" dimension of the Chronic Treatment Acceptance (ACCEPT) questionnaire

End point description:

ACCEPT questionnaire is generic medication acceptance measure assessing how participants weigh advantages and disadvantages of long-term medication. It consists 25 items, capture six dimensions.3 questions focus on general acceptance of study medication will be analyzed. Items on scale are rated1-5 scores:1:totally disagree,2:somewhat disagree,3:somewhat agree,4:totally agree and 5:I don't know. Total score of dimension is calculated as mean of recoded items of dimension and linearly transformed to scale from 0-100. Total Score=(mean of recoded items in dimension minus1)divided by2*100.LOCF was primary method of analysis. Measure type is mean for adjusted mean and dispersion measure: 95% CI. Baseline value is latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed(represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline and at Weeks 8, 24 and 48

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[159]	308[160]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 8, n=302, 287	8.9 (6.3 to 11.6)	1.0 (-1.7 to 3.8)		
Week 24, n=303, 295	12.3 (9.9 to 14.8)	5.5 (3.0 to 8.0)		
Week 48, n=302, 298	13.7 (11.2 to 16.3)	3.0 (0.4 to 5.6)		

Notes:
[159] - ITT-E Population
[160] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Treatment comparison at Week 8 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	7.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.1
upper limit	11.7

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Treatment comparison Week 24 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.3
upper limit	10.4

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: Treatment comparison at Week 48 for the groups CAB LA+ RPV LA and current ART is presented	
Comparison groups	CAB LA+RPV LA (Q4W) v Current ART

Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	10.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	14.4

Secondary: Change from 4b in tolerability of injection at Week 5, 40 and 41 using numeric rating scale (NRS) within CAB LA+RPV LA arm

End point title	Change from 4b in tolerability of injection at Week 5, 40 and 41 using numeric rating scale (NRS) within CAB LA+RPV LA arm[161]

End point description:

The NRS questionnaire is used to assess the tolerability of injections in CAB LA+RPV LA arm only. The questionnaire consists of one single question and will assess maximum level of pain experienced with the most recent injections ranking from no pain (0) to extreme pain (10). Missing scores was imputed using LOCF. Only those participants with data available at the specified data points were analyzed

End point type	Secondary

End point timeframe:

Weeks 4b, 5, 40 and 41

Notes:

[161] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

End point values	CAB LA+RPV LA (Q4W)			
Subject group type	Reporting group			
Number of subjects analysed	278[162]			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 5	2.0 (± 2.94)			
Week 40	0.5 (± 2.79)			
Week 41	0.4 (± 2.83)			

Notes:

[162] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in individual item scores of HIVTSQc at Weeks 4b, 24 and 44

End point title	Change from Baseline in individual item scores of HIVTSQc at

	Weeks 4b, 24 and 44

End point description:

HIVTSQc is a 12 item questionnaire. The individual treatment change item scores on HIVTSQc scale are rated as +3 ('much more satisfied', 'much more convenient', 'much more flexible',etc.) to -3 ('much less satisfied', 'much less convenient', 'much less flexible', etc.). The higher the score, the greater the improvement in satisfaction with each aspect of treatment and the lower the score, the greater the deterioration in satisfaction with each aspect of treatment. LOCF was used as primary method of analysis. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles). 99999 indicates data was not available due to insufficient participants.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4b, 24 and 44

End point values	CAB LA+RPV LA (Q4W)	Current ART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308[163]	308[164]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Item 1; Week 4b; n=294, 0	0.3 (± 1.42)	99999 (± 99999)		
Item 1; Week 24; n=300, 287	0.4 (± 1.46)	-0.1 (± 1.04)		
Item 1; Week 44; n=300, 293	0.5 (± 1.42)	-0.1 (± 1.21)		
Item 2; Week 4b; n=295, 0	0.0 (± 0.60)	99999 (± 99999)		
Item 2; Week 24; n=300, 287	0.1 (± 0.70)	0.0 (± 0.68)		
Item 2; Week 44; n=300, 293	0.1 (± 0.84)	-0.1 (± 0.82)		
Item 3; Week 4b; n=295, 0	0.4 (± 1.35)	99999 (± 99999)		
Item 3; Week 24; n=300, 288	0.3 (± 1.47)	0.1 (± 1.12)		
Item 3; Week 44; n=300, 294	0.3 (± 1.45)	0.0 (± 1.26)		
Item 4; Week 4b; n=295, 0	0.3 (± 1.21)	99999 (± 99999)		
Item 4; Week 24; n=300, 288	0.5 (± 1.29)	-0.0 (± 1.16)		
Item 4; Week 44; n=300, 294	0.4 (± 1.30)	-0.1 (± 1.22)		
Item 5; Week 4b; n=295, 0	0.5 (± 1.24)	99999 (± 99999)		
Item 5; Week 24; n=300, 288	0.8 (± 1.32)	0.1 (± 1.31)		
Item 5; Week 44; n=300, 294	0.8 (± 1.42)	0.0 (± 1.37)		
Item 6; Week 4b; n=294, 0	0.5 (± 1.63)	99999 (± 99999)		
Item 6; Week 24; n=299, 288	0.8 (± 1.77)	0.2 (± 1.79)		
Item 6; Week 44; n=299, 293	0.9 (± 1.72)	0.2 (± 1.78)		
Item 7; Week 4b; n=295, 0	0.2 (± 0.90)	99999 (± 99999)		
Item 7; Week 24; n=300, 288	0.2 (± 0.94)	0.1 (± 1.00)		
Item 7; Week 44; n=300, 294	0.2 (± 0.99)	0.2 (± 1.08)		
Item 8; Week 4b; n=294, 0	0.3 (± 1.21)	99999 (± 99999)		
Item 8; Week 24; n=299, 288	0.7 (± 1.27)	0.1 (± 1.20)		
Item 8; Week 44; n=299, 294	0.6 (± 1.31)	0.0 (± 1.27)		

Item 9; Week 4b; n=294, 0	0.4 (± 1.22)	99999 (± 99999)		
Item 9; Week 24; n=299, 288	0.6 (± 1.27)	0.1 (± 1.20)		
Item 9; Week 44; n=299, 294	0.5 (± 1.32)	0.0 (± 1.25)		
Item 10; Week 4b; n=293, 0	0.8 (± 1.44)	99999 (± 99999)		
Item 10; Week 24; n=298, 287	1.2 (± 1.56)	0.3 (± 1.38)		
Item 10; Week 44; n=298, 293	1.1 (± 1.64)	0.2 (± 1.60)		
Item 11; Week 4b; n=292, 0	0.4 (± 1.23)	99999 (± 99999)		
Item 11; Week 24; n=297, 287	0.7 (± 1.31)	0.1 (± 1.28)		
Item 11; Week 44; n=297, 293	0.6 (± 1.45)	0.1 (± 1.38)		
Item 12; Week 4b; n=293, 0	0.3 (± 1.41)	99999 (± 99999)		
Item 12; Week 24; n=298, 287	0.0 (± 1.52)	0.1 (± 1.14)		
Item 12; Week 44; n=298, 293	0.0 (± 1.58)	0.2 (± 1.17)		

Notes:

[163] - ITT-E Population

[164] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with different demographic parameters for inter-subject variability

End point title	Number of participants with different demographic parameters for inter-subject variability

End point description:

Blood samples were planned to be collected at indicated time points for PK analysis of CAB LA and RPV LA. Demographic parameters including, but not limited to, age, sex, race, body weight, body mass index, and relevant laboratory parameters were planned to be evaluated as potential predictors of inter subject variability for pharmacokinetic parameters. This was an exploratory Outcome Measure. Data will not be analyzed and reported.

End point type	Secondary

End point timeframe:

Upto Week 48

End point values	CAB LA	RPV LA		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[165]	0[166]		
Units: Participants				

Notes:

[165] - PK Population

[166] - PK Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to Week 52	
Adverse event reporting additional description:	
AEs and SAEs were collected in Safety population.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	CAB LA+RPV LA (Q4W)
Reporting group description:	
During Maintenance phase (Day 1-Week 52), participants received oral CAB 30 milligram (mg)+RPV 25 mg once daily from Day 1 for 4 weeks. At Week 4B, the participants were given the last dose of oral CAB+RPV and the first dose of CAB LA 600 mg+RPV LA 900 mg injections within 2 hours of the final oral dose. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg every four weeks (Q4W) through Week 52. After completion of Maintenance phase, participants who chose to enter Extension phase continued to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period	
Reporting group title	Current ART
Reporting group description:	
During Maintenance phase (Day 1 - Week 52), participants continued to receive current antiretroviral therapy (ART) (protease inhibitor [PI] or integrase inhibitor [INI] or non-nucleoside reverse transcriptase inhibitor [NNRTI]) plus 2 NRTIs for 52 weeks. After completion of the Maintenance phase, participants who chose to enter the Extension phase switched to CAB LA+RPV LA	

Serious adverse events	CAB LA+RPV LA (Q4W)	Current ART	
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 308 (4.22%)	14 / 308 (4.55%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Seminoma			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Liver function test abnormal			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye injury			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skull fracture			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion missed			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion spontaneous			

subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 308 (0.00%)	2 / 308 (0.65%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury			

subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Respiratory distress			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Hepatitis A			
subjects affected / exposed	1 / 308 (0.32%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			

subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Escherichia coli			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 308 (0.00%)	1 / 308 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 308 (0.32%)	0 / 308 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	CAB LA+RPV LA (Q4W)	Current ART	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	263 / 308 (85.39%)	117 / 308 (37.99%)	
Nervous system disorders			
Headache			
subjects affected / exposed	34 / 308 (11.04%)	17 / 308 (5.52%)	
occurrences (all)	48	19	
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	231 / 308 (75.00%)	0 / 308 (0.00%)	
occurrences (all)	1208	0	
Injection site nodule			
subjects affected / exposed	37 / 308 (12.01%)	0 / 308 (0.00%)	
occurrences (all)	54	0	
Injection site induration			
subjects affected / exposed	30 / 308 (9.74%)	0 / 308 (0.00%)	
occurrences (all)	54	0	
Pyrexia			
subjects affected / exposed	21 / 308 (6.82%)	9 / 308 (2.92%)	
occurrences (all)	29	9	
Fatigue			
subjects affected / exposed	22 / 308 (7.14%)	6 / 308 (1.95%)	
occurrences (all)	29	9	
Injection site swelling			
subjects affected / exposed	23 / 308 (7.47%)	0 / 308 (0.00%)	
occurrences (all)	48	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	22 / 308 (7.14%)	15 / 308 (4.87%)	
occurrences (all)	24	17	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	16 / 308 (5.19%)	14 / 308 (4.55%)	
occurrences (all)	20	16	
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	20 / 308 (6.49%)	10 / 308 (3.25%)	
occurrences (all)	22	12	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	52 / 308 (16.88%)	42 / 308 (13.64%)	
occurrences (all)	87	58	
Upper respiratory tract infection			
subjects affected / exposed	32 / 308 (10.39%)	25 / 308 (8.12%)	
occurrences (all)	48	30	
Influenza			
subjects affected / exposed	17 / 308 (5.52%)	14 / 308 (4.55%)	
occurrences (all)	19	15	
Respiratory tract infection viral			
subjects affected / exposed	11 / 308 (3.57%)	17 / 308 (5.52%)	
occurrences (all)	12	23	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 September 2016	Amendment No.1: requirements for South Korea; update I/E criteria age per local regulatory; add IP labels to Appendix 8.
02 November 2016	Amendment No.2: requirements for Sweden; protocol details and clarifications requested by MPA.
13 December 2016	Amendment No.3: contact MM if rash occurs during OLI period; add lipid objective and endpoint; IP dosing at Day 1 visit clarity; allow serum pregnancy testing instead of urine testing when not available; CAB, RPV exposure may persist for more than 1 year after IM injections; use of HAART for 1 year after last CAB+RPV injection, females use adequate contraception for 1 year after last CAB+RPV injection; treatment with glucocorticoids up to 21 days; definition of change in ART regimen for I/E criteria; contact MM upon serofast RPR result for screening syphilis test; remove requirement to record frequency of IP taken and treatment delays or dose reductions of IP in eCRF; indicate drugs known to cause TdP to be used with caution with RPV; remove limits on duration of topical imiquimod; clarity on reflexive testing for HBV DNA for participants with + anti-HBc, - HBsAg, - anti-HBs results; temperature collection to T&E table; site plans for managing risks for suicide related events; PK sample window collection clarity; PRO timings clarification; prohibited meds clarification; remove collection of pregnancy information for female partners of male study participants; details of injection device for IM administration collected within eCRF; local labs approved by MM for eligibility in special circumstances; screening HLA-B*5701 result is not required for eligibility status.
07 November 2017	Amendment No.4: potential rollover of participants to study 207966; snapshot virologic response replaced with proportion of participants with plasma HIV-1 RNA < 50 c/mL over time; exploratory analyses evaluating virologic, immunologic responses in treatment arms limited to Week 48 analysis; pregnancy and follow-up pregnancy event form report timing updated; updated references for CAB, RPV IBs.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported